Preg-CoV Evaluating COVID-19 Vaccines in Pregnancy

A PHASE II, RANDOMISED, SINGLE-BLIND, PLATFORM TRIAL TO ASSESS SAFETY, REACTOGENICITY AND IMMUNOGENICITY OF COVID-19 VACCINES IN PREGNANT WOMEN IN THE UNITED KINGDOM

Trial Title	Covid-19 vaccines in pregnancy (Preg-CoV)
Protocol number	5.0
Trial Sponsor	St George's, University of London
REC reference	**21/NE/0114**
IRAS number	301115

PARTICIPANT INFORMATION SHEET

Princess Royal Hospital (The Shrewsbury & Telford Hospital NHS Trust) would like to invite you to take part in our trial looking at COVID-19 vaccination in pregnancy. We aim to recruit, vaccinate and follow-up pregnant women across the UK in order to look at the safety of, and immune responses to, COVID-19 vaccines in pregnant women and their babies.

To help you decide whether you would like to take part in the trial, we have put together this information sheet which details key information related to the trial and what it will involve. Please read the following information carefully and consider discussing it with friends, relatives, or others as you wish. You are welcome to ask us about anything that may not be clear.

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Why is this trial being performed?

The virus and disease

Towards the end of 2019 and beginning of 2020, a new virus subsequently named SARS-CoV2, emerged and was found to cause a disease called COVID-19. The virus has spread across the world causing a pandemic. Almost simultaneously, work began on developing vaccines against this virus with the aim of helping prevent severe disease, hospitalisation and death.

COVID-19 can present with a spectrum of symptoms. Common symptoms of infection with the virus include fever, tiredness, dry cough, shortness of breath and changes to the senses of smell and taste. The majority of infected people will have no or mild symptoms and will recover from the infection without needing special treatment. However, approximately 10-15% of cases (2-3 in 20) progress to develop severe symptoms, and about 5% (1 in 20) become critically ill.

COVID-19 and pregnancy

Studies looking specifically at pregnant women in the UK show that pregnant women are no more likely to get COVID-19 than other healthy non-pregnant adults. Approximately 2 in 3 pregnant women with COVID-19 will have no symptoms, and those pregnant women who do have symptoms will usually have mild symptoms. However, a small number of pregnant women can become unwell with COVID-19, with the risk of severe illness being greater in the third trimester. Compared to non-pregnant women with COVID-19, pregnant women with COVID-19 have higher rates of intensive care unit admission and compared to pregnant women without COVID-19, pregnant women have overall worse maternal outcomes.

The studies have also found that women from black, Asian and minority ethnic backgrounds are more likely than other women to be admitted to hospital for COVID-19. Other risk factors that increase the chances of pregnant women developing severe COVID-19 disease and requiring hospital admission are being aged 35 years and over, having a body mass index (BMI) of 25 or more and having health conditions such as high blood pressure and diabetes. The risk of developing severe illness with COVID-19 in pregnancy has also been shown to be increased in women living in areas or households with increased socioeconomic deprivation.

In pregnant women who become infected with COVID-19, there is currently no evidence to suggest that it causes any problems with development of their babies or that infection in early pregnancy increases the chance of miscarriage. Transmission of the virus from a pregnant woman to her baby in pregnancy or during childbirth has so far been shown to be very uncommon. In most cases of COVID-19 in newborn babies, the babies remain well. However pregnant women who become very unwell with COVID-19 are two to three times more likely to have their baby early.

COVID-19 vaccination in pregnancy

Currently, three vaccines have been approved for use in the national immunisation programme in the UK for COVID-19 in adults: AstraZeneca, Pfizer and Moderna. Other vaccines such as Novavax are expected to be approved in the near future.

The main trial studies for these vaccines did not include pregnant women. However, no specific safety concerns have thus far been identified with any COVID-19 vaccines in relation to pregnancy. In the United States, over 100,000 pregnant women have already been vaccinated as part of their national vaccine roll-out.

The current recommendation from the Joint Committee on Vaccination and Immunisation (JCVI), the body that advises UK health departments on immunisation, is that pregnant women should be offered vaccination at the same time as non-pregnant women based upon their age and at-risk group. Women who are breast-feeding may also be offered any suitable COVID-19 vaccine.

This trial

By performing this trial, we aim to gather further specific data on the safety of COVID-19 vaccines in pregnant women and their babies. We will also compare the immune responses to different COVID-19 vaccines in pregnant women and their babies and look at whether the stage of pregnancy and the intervals between vaccine doses makes a difference.

What vaccines are being used in this trial?

COVID-19

Currently, the COVID-19 vaccines that are to be studied in this trial are:

- Pfizer/BioNTech BNT162b2 – hereafter referred to as **Pfizer**
- COVID-19 Vaccine Moderna – hereafter referred to as **Moderna**
- Novavax NNVXCoV2373 – hereafter referred to as **Novavax (will ONLY be used in trial when it is approved for use in the UK)**
- AstraZeneca ChAdOx1 nCOV-19 – hereafter referred to as **AstraZeneca (will ONLY be used for participants who have received one dose of the vaccine already (pre-trial) and are in Cohort 4 - please see later sections of this information sheet for details of the trial cohorts)**

The Pfizer, Moderna and AstraZeneca vaccines have been approved for emergency use in the UK under regulation 174 of the Human Medicines Regulations 2012. The Novavax vaccine has been tested in clinical trials that have enrolled over 45 000 people; and has been shown to be highly effective at preventing COVID-19. The process of obtaining approval for emergency use of this vaccine by the UK Medicines Healthcare Regulatory Agency (MHRA) has commenced, but as of 01 June 2021 approval is pending. All of the COVID-19 vaccines in this trial follow a 2-dose schedule. Further details about each of the individual vaccines are given below:

Pfizer:

This is a messenger RNA (mRNA) vaccine. This vaccine uses a small amount of the genetic coding material (mRNA) of the SARS-CoV-2 spike (S) protein packaged inside very small fatty particles (lipid nanoparticles). When these are injected into your body, your cells take up these fatty particles, and then start producing the SARS-CoV-2 spike protein. Your immune system then "sees" these spike proteins and makes a protective immune reaction against them. The original mRNA that has been taken into your cells is broken down within a few days and cannot be incorporated into your own genetic code.

This vaccine has been tested in more than 40,000 people worldwide and has been shown to be both safe and effective in preventing COVID-19.

Moderna:

This is also an mRNA vaccine, so works in a similar way to the Pfizer vaccine. This vaccine has been tested in more than 30,000 people worldwide and has been shown to be both safe and effective in preventing COVID-19.

Novavax:

This vaccine is based on the spike protein from the SARS-CoV-2 virus in combination with an adjuvant, a substance that increases the response of the immune system to the protein. The adjuvant is called "Matrix-M1™" and consists of saponin (which is derived from the soapbark tree) and natural fats. It has been tested in over 40,000 people (including a large trial of 15,000 people in the UK) and is safe and effective.

AstraZeneca:

The AstraZeneca vaccine is made from a virus (ChAdOx1), which is a weakened version of a common cold virus (adenovirus). This has been genetically changed so that it is impossible for it to grow in humans. Added to this virus is a small amount of the genetic coding material of the SARS-CoV-2 spike (S) protein, which plays an essential role in SARS-CoV-2 infection. Your cells then start producing the SARS-CoV-2 spike protein. Your immune system then "sees" these spike proteins, and makes a protective immune reaction against them that helps stop SARS-CoV-2 infections.

The AstraZeneca vaccine has been tested in more than 50,000 people worldwide and has been found to be both safe and effective in preventing COVID-19. However, since deployment, extremely rare cases of blood clots with low levels of platelets (a component of blood) have been observed following vaccination with this vaccine. The majority of these cases occurred within the first 14 days following vaccination but some have also been reported after this period. If you had no such complications after the first dose, the current guidance is that a second dose of the vaccine can be given.

None of these vaccines contain live SARS-CoV-2 coronavirus and therefore cannot give you COVID-19. The potential side effects of these vaccines are discussed in more detail in the section 'What are the possible disadvantages of taking part?'.

If further vaccines become approved for use in the UK whilst this trial is running, they may be included in the trial.

Pertussis (Whooping cough)

If you have not already had the whooping cough vaccine in this pregnancy, you will also be offered this as part of the trial. Whooping cough (pertussis) is the name given to the disease of the airways caused by the bacteria *Bordetella pertussis*. The whooping cough vaccine has been offered to all pregnant women in the UK since 2012. It is usually given between 16 and 32 weeks of pregnancy so that it is able to provide protection for the baby against whooping cough in the first few months of life. Over 70% of pregnant women in the UK routinely receive this vaccine.

The whooping cough vaccine recommended for use in pregnancy in the UK since 2014 is a low dose diphtheria, tetanus, pertussis (acellular component) and poliomyelitis (inactivated) vaccine (dTaP/IPV).

Why have I been chosen, and do I have to take part?

You have been approached about this trial because you are pregnant. You do not have to take part and the decision on whether or not to do so is entirely up to you. If you do choose to take part, you will be given this information sheet to keep (or be sent it electronically) and will be asked to sign a consent form. You are free to withdraw at any time and without having to give a reason, but you may be asked to come for an extra visit for a follow up appointment for safety reasons. If you do not wish to take part in this trial or you choose to take part and then decide to withdraw from the trial before the end, your care will not be affected in any way.

Am I suitable to take part?

Pregnant women expecting one baby, aged 18 to 45 years can take part. To be enrolled in the trial:

- You must be willing to tell the trial staff about your medical history, and you may be asked to allow the trial staff to check this with your General Practitioner (GP). Bear in mind that we would also notify your GP if you joined the trial.

You cannot take part in this trial if you:

- Have had a lab confirmed diagnosis of COVID-19 (by swab PCR) in the past
- Have already received two doses of the COVID-19 vaccine
- Are already taking part in any trial looking to prevent COVID-19 through vaccines or medications
- Have had any vaccine in the 30 days before or after this trial vaccine. The exceptions to this are the seasonal influenza and dTaP/IPV (whooping cough) vaccines. If you are offered these by your GP or your place of work, we ask that you have these at least 7 days before or after you receive either of the two trial vaccine doses but would prefer that you have the dTaP/IPV vaccine as part of the trial.
- Have received a transfusion of any blood products, or immunoglobulins (antibodies) in the 3 months before having the trial vaccine
- Have immunosuppression or immunodeficiency – this includes being on medications that reduce the immune system such as methotrexate and steroid tablets
- Have ever had a severe allergic reaction (anaphylaxis)
- Have an allergy to any of the component of the COVID vaccines used in this trial, including polyethylene glycol/macrogol (PEG). PEGs are a group of known allergens commonly found in medicines, many household products and cosmetics, and are contained in the BNT162b2 (Pfizer/BioNTech) vaccine. Known allergy to PEG is very rare.
- Have a history of major illness that may impact on this pregnancy based upon the clinical judgement of the trial team

What happens if I take part?

If you decide to take part, we will ask to you to attend for at least 9 scheduled visits during and after your pregnancy and complete an e-diary between some visits. The total number of visits you will need to attend will depend upon the stage of your pregnancy you are at when you join the trial. The visits will take place at the hospital your pregnancy is booked at.

There will be 4 cohorts in the trial (see table 1 below); the cohort you join will be dependent on your stage of pregnancy when joining the trial, whether you have already received a recommended whooping cough vaccine in the pregnancy and whether you have already received a first dose of a recommended COVID-19 vaccine before this pregnancy. With the exception of cohort 4, once you are placed into your cohort, you will be 'randomised' to a particular arm in that cohort, which will determine which COVID-19 vaccine you receive. You will be 'blinded' i.e., you will not know which COVID-19 vaccine you have received until the trial is completed.

	Pre-Pregnancy/ 1st Trimester	First Dose	Short Booster (4-6 weeks after first dose)	Long Booster (8-12 weeks after first dose)	Postnatal Booster (4-12 weeks after first dose)
COHORT 1 13^{+0}-23^{+6} weeks		Vaccine A	Pertussis* vaccine	Vaccine A	No vaccine
		Vaccine A	Vaccine A	Pertussis* vaccine	No vaccine
		Vaccine B	Pertussis* vaccine	Vaccine B	No vaccine
		Vaccine B	Vaccine B	Pertussis* vaccine	No vaccine
		Vaccine C	Pertussis* vaccine	Vaccine C	No vaccine
		Vaccine C	Vaccine C	Pertussis* vaccine	No vaccine
COHORT 2 24^{+0}-27^{+6} weeks		Vaccine A	No vaccine	Vaccine A	No vaccine
		Vaccine A	Vaccine A	No vaccine	No vaccine
		Vaccine B	No vaccine	Vaccine B	No vaccine
		Vaccine B	Vaccine B	No vaccine	No vaccine
		Vaccine C	No vaccine	Vaccine C	No vaccine
		Vaccine C	Vaccine C	No vaccine	No vaccine
COHORT 3 28^{+0}-34^{+0} weeks		Vaccine A	No vaccine	No vaccine	Vaccine A
		Vaccine B	No vaccine	No vaccine	Vaccine B
		Vaccine C	No vaccine	No vaccine	Vaccine C
COHORT 4 13^{+0}-34^{+0} weeks	First dose	No vaccine	Booster dose of the vaccine already received, given either by 25+6 **OR** from 26+0		No vaccine

Table 1. Cohort and arms in the trial indicating vaccines given as part of trial; *Pertussis = Whooping cough vaccine

Visits will include various trial procedures e.g. blood sample taking, and usually take place at the trial site unless alternative plans are made by the trial team. If you were to develop symptoms suggestive of COVID-19 disease, you may be asked to attend for additional unscheduled visits.

Your participation in the trial will be required up to 12 months after your baby is born. Once you are enrolled onto the trial, we will inform your GP of your participation. We will also inform them at the

end of the trial. In certain circumstances we may need to contact your GP and/ or obstetric team to gather further information about your medical and/ or pregnancy history.

Visit schedule

The schedule of visits you are assigned to will be determined by the cohort you are allocated to (as mentioned above, this is dependent on how far along you are in your pregnancy when recruited.)

Cohort 1

If you are between 13+0 – 23+6 weeks of gestation and have *not* already had the whooping cough vaccine, you will be placed in Cohort 1 with up to 11 scheduled visits. At one of these visits, before you deliver, you will also be given the whooping cough vaccine as part of the study (and so will not have to go to your GP or antenatal clinic to get this). Incorporation of the whooping cough vaccine will allow the trial team to blind you to the dosing schedule (short versus long interval) of the COVID-19 vaccinations.

Cohort 2

If you are between 24+0 – 27+6 weeks of gestation. You will be placed in Cohort 2 with up to 11 scheduled visits. You will receive both doses of a COVID-19 vaccine at visits before delivery.

Cohort 3

If you are between 28+0 – 34+0 weeks of gestation, you will have 9 scheduled visits. You will receive the first dose of a COVID-19 vaccine at a trial visit before delivery and the second dose at a trial visit after delivery.

Cohort 4

If you are between 13+0 – 34+0 weeks of gestation and received the first dose of a COVID-19 vaccine before you were pregnant or when in the first trimester of your pregnancy, and have not yet had the second dose of the vaccine, you will be placed in Cohort 4. You will receive the second dose of vaccine at a visit before your delivery either before 25+6 OR after 26+0 weeks of gestation.

Breast milk sub-study

You may also be invited to take part in a breast milk sub-study if you are planning to breastfeed your baby. This will look at the immune response to the vaccination passed on in your breast milk. If you are happy to take part, we will collect samples of colostrum within the first 72 hours after delivery and then breast milk samples at later visits. Participation in this sub-study is entirely optional and will be at selected trial sites only.

Please note: if you are placed in cohorts 2, 3 or 4 it may be possible for to you to receive the whooping cough vaccine with us in the trial, at a trial visit when you are between 16+0 to 32+0 weeks gestation. Otherwise we would advise you to go to your GP or antenatal clinic to get this. The whooping cough vaccination should be given at least 7 days before or after a COVID-19 vaccination in the trial.

The following sections give further details about what will happen at each trial visit and indicative times of how long each visit will take – please refer to your specific cohort.

Specific trial visits – COHORT 1

Visit Number	Screening + V1	V2	V3	V4	V5	V6	V7	V8[A]	V9	V10	V11	V12
Study Day	**0**	**14**	**28-42**	**56-84**	**84-112**	**112-140[¥]**	**DELIVERY**	**0-7 after delivery**	**12-16 after delivery**	**28-42 OR 70-84 after delivery**	**182 after delivery**	**364 after delivery**
Location	Trial site	Telephone	Trial site	Trial site	Trial site	Trial site	Delivery site	Visit ONLY if BM sub-study (Home/ trial site)[A]	Telephone (Home/ trial site if in BM sub-study)	Home/ Trial site	Telephone	Home/ Trial site
Main activities	Consent Screening Examination E-diary set-up	Review	Review	Review	Review	Review	Review	Review[A]	Review	Review	Review	Review Baby assessment
Blood tests	Maternal		Maternal	Maternal	Maternal	Maternal	Cord Blood* Maternal			Maternal Baby		Maternal
Breast milk (BM) collection (optional)								Colostrum*	Breast milk*			
Short Interval Boost	Covid-19		Covid-19	Pertussis**								
Long Interval Boost	Covid-19		Pertussis**	Covid-19								

*Cord blood samples + breast milk samples will be taken at selected sites only; if unable to get cord blood sample, we would ask you whether we may obtain a baby blood sample in the first week instead; **Pertussis = Whooping cough; [¥] This visit will only take place if you have not yet delivered; [A] You will only have a visit 8 if you decide to take part in the breast milk sub-study

COHORT 1: Screening and Visit 1 – Maternal Visit [1.5 – 2 hours]

This visit will take place when you are between 13+0 – 27+6 weeks in your pregnancy at the trial site.

At this visit, we will check that you are eligible to be enrolled onto the trial and discuss the trial with you. You will then be asked to sign a consent form. We will collect some demographic details from you including your NHS number, and information about your general health, medication history and your pregnancy. You will then have a brief medical examination, your height and weight checked and blood tests taken.

Following this, you will be randomly assigned an 'arm' in your cohort. This will determine which COVID-19 vaccine you will receive, and whether you will be given the second dose after a short interval (4-6 weeks) or a long interval (8-12 weeks). This means that the COVID-19 vaccine you will receive in the study will be selected at random; the team will know the vaccine you are given but you will not know until the end of the study.

At this visit, you will be then given the 1st dose of the vaccine you are assigned. Vaccination will be done by members of the trial team who are trained and experienced in vaccine administration and in emergency procedures in the event of an allergic reaction. They will have access to emergency medication and equipment. After vaccination, we will ask you to remain with us for 20 minutes of observation and during this time we will show you how to complete an e-diary. We ask that you complete this daily for 28 days following vaccination.

COHORT 1: Visit 2 – Maternal Visit [Telephone call]

This visit will take place 14 (+/- 7) days after your first vaccination via telephone. We will review your e-diary and enquire about your health since your 1st vaccination.

COHORT 1: Visit 3 – Maternal Visit [1.5 hours]

This visit will take place 28-42 days after your first vaccination at the trial site. We will review your e-diary, enquire about your health since your 1st vaccination, perform a brief examination (if indicated) and take blood samples. If you are in a short interval booster arm, you will then be given the second dose (booster) of your assigned COVID-19 vaccine. If you are in a long interval booster arm, you will be given your whooping cough vaccine. You will not know whether you have received a booster or the whooping cough vaccine - this is so that you remain 'blinded' (i.e. do not find out during the study) to the COVID-19 vaccine dosing schedule you are on. Following vaccination, we will ask you to remain with us for 20 minutes of observation. We will again ask you to complete a daily e-diary for 28 days.

COHORT 1: Visit 4 – Maternal Visit [1.5 hours]

This visit will take place 56-84 days following your first vaccination OR 28-42 days after your booster dose if you have already had this, at the trial site. We will review your e-diary, enquire about your health since your previous visit, perform a brief examination (if indicated) and take blood samples. If you are in the short interval booster arm, you will be given the whooping cough vaccine at this visit. If you are in the long booster arm, you will be given the second dose of your assigned COVID-19 vaccine. You will not know whether you have received a booster or the whooping cough vaccine - this is so that you remain 'blinded' (i.e. do not find out during the study) to the COVID-19 vaccine dosing schedule you are on. Following vaccination, we will ask you to remain with us for 20 minutes of observation. We will again ask you to complete a daily e-diary for a further 28 days.

COHORT 1: Visit 5 – Maternal Visit [30 minutes]

This visit will take place 84-122 days after your first vaccination OR 28-42 days after your booster dose if you are in the long interval booster arm, at the trial site. We will review your e-diary if you are in the long interval booster arm and were vaccinated with a COVID-19 vaccine at visit 3, enquire about your health since your previous visit, perform a brief medical examination (if indicated) and take blood samples.

COHORT 1: Visit 6 – Maternal visit [30 minutes]

This visit will take place 112-140 days after your first vaccination OR 56-84 days after your booster dose if you are in the long interval booster arm. We will enquire about your health since your previous visit, perform a brief examination (if indicated) and take blood samples.

COHORT 1: Visit 7 – Maternal and baby, at delivery

This visit will coincide with your delivery. After delivery, we will take a blood sample from you and an umbilical cord blood sample (to be taken at selected trial sites only). These samples may be taken by a member of the trial team or a member of the clinical team looking after you at the time. If it is not possible to take a blood or cord sample at delivery, we will ask you if we may take a blood sample from you and your baby in the first week following delivery. If you decide to breastfeed your baby and have consented to take part in the sub-study investigating immunity in breast milk after vaccination, we will provide you with information on how to collect a colostrum sample and provide you with containers in preparation to do so.

COHORT 1: Visit 8 – Maternal, after delivery (ONLY if in breast milk sub-study) [30 minutes – 1 hour]

This visit will only occur if you decide to take part in the breast milk sub-study. If so, it will take place 0-7 days after your delivery at home or at the trial site. We will enquire about your health since delivery. If you are taking part in the breast milk sub-study, this visit will take place in the hospital or at your home and we will ask you to provide a 1-2mls sample of colostrum.

COHORT 1: Visit 9 – Maternal, after delivery [Telephone call or 30 minutes if taking place on-site/ home]

This visit will take place 12-16 days after your delivery via telephone. We will enquire about your health since delivery. If you are taking part in the breast milk sub-study, this visit will take place at the trial site or at your home and we will ask you to provide a 2-5mls sample of breast milk.

COHORT 1: Visit 10 – Maternal, after delivery [1 hour]

This visit will take place 28-42 days **OR** 70-84 days (decided by randomisation) after your delivery, either at the trial site or at your home. We will enquire about your health and perform a brief medical examination (if indicated). We will also collect a blood sample from your baby (about 1 teaspoonful); this will be taken by an experienced member of the trial team.

COHORT 1: Visit 11 – Maternal, after delivery [Telephone call]

This visit will take place 142-166 days after your delivery, via telephone, where we will enquire about your health.

COHORT 1: Visit 12 – Maternal, after delivery [1.5– 2 hours]

This visit will take place 349-379 days after your delivery, either at the trial site or at your home. We will enquire about your health, perform a brief examination of you if indicated, and collect a blood sample. We will also perform a developmental assessment of your baby using a questionnaire if this has not already been done during their routine healthcare.

Specific trial visits – COHORT 2

Visit Number	Screening + V1	V2	V3	V4	V5	V6	V7	V8[A]	V9	V10	V11	V12
Study Day	**0**	**14**	**28-42**	**56-84**	**84-112**	**112-140[¥]**	**DELIVERY**	**0-7 after delivery[A]**	**12-16 after delivery**	**28-42 OR 70-84 after delivery**	**182 after delivery**	**364 after delivery**
Location	Trial site	Telephone	Trial site	Trial site	Trial site	Trial site	Delivery site	Visit ONLY if BM sub-study (Home/ trial site)[A]	Telephone (Home/ trial site if in BM sub-study)	Home/ Trial site	Telephone	Home/ Trial site
Main activities	Consent Screening Examination E-diary set-up	Review	Review	Review	Review	Review	Review Baby examination	Review[A]	Review	Review	Review	Review Baby assessment
Blood tests	Maternal		Maternal	Maternal	Maternal	Maternal	Cord Blood* Maternal			Maternal Baby		Maternal
Breast milk (BM) collection (optional)								Colostrum*	Breast milk*			
Short Interval Boost	Covid-19		Covid-19									
Long Interval Boost	Covid-19			Covid-19**								

* Cord blood samples + breast milk samples will be taken at selected sites only; if unable to get cord blood sample, we would ask you whether we may obtain a baby blood sample in the first week instead; [¥] This visit will only take place if you have not yet delivered; **Long interval dose must be given by 36+0 weeks gestation; [A] You will only have a visit 8 if you decide to take part in the breast milk sub-study

COHORT 2: Visit 1 – Maternal Visit [1.5 – 2 hours]

This visit will take place when you are between 24+0 – 27+6 weeks in your pregnancy at the trial site.

At this visit, we will check that you are eligible to be enrolled onto the trial and discuss the trial with you. You will then be asked to sign a consent form. We will collect some demographic details from you including your NHS number, and information about your general health, medication history and your pregnancy. You will then have a brief medical examination, your height and weight checked and blood tests taken.

Following this you will be randomly assigned an 'arm' in your cohort. This will determine which COVID-19 vaccine you will receive, and whether you will be given the second dose after a short interval (4-6 weeks) or a long interval (8-12 weeks). This means that the COVID-19 vaccine you will receive in the study will be selected at random; the team will know the vaccine you are given but you will not know until the end of the study.

At this visit, you will be then given the 1st dose of the vaccine you are assigned. Vaccination will be done by members of the trial team who are trained and experienced in vaccine administration and in emergency procedures in the event of an allergic reaction. They will have access to emergency medication and equipment. After vaccination, we will ask you to remain with us for 20 minutes of observation and during this time we will show you how to complete an e-diary. We ask that you complete this daily for 28 days following vaccination.

COHORT 2: Visit 2 – Maternal Visit [Telephone call]

This visit will take place 14 (+/- 7) days after your first vaccination via telephone. We will review your e-diary and enquire about your health since your 1st vaccination.

COHORT 2: Visit 3 – Maternal Visit [30 minutes -- 1.5 hours]

This visit will take place 28-42 days after your first vaccination, at the trial site. We will review your e-diary, enquire about your health since your 1st vaccination, perform a brief examination (if indicated) and take blood samples. If you are in a short interval booster arm, you will then be given the second dose (booster) of your assigned COVID-19 vaccine. Following vaccination, we will ask you to remain with us for 20 minutes of observation. If you have been vaccinated at this visit, we will again ask you to complete a daily e-diary for 28 days.

COHORT 2: Visit 4 – Maternal Visit [30 minutes - 1.5 hours]

This visit will take place 56-84 days following your first vaccination OR 28-42 days after your booster dose if you have already had this, at the trial site. We will review your e-diary if you are in the short interval booster arm and were vaccinated at visit 3, enquire about your health since your previous visit, perform a brief medical examination (if indicated) and take blood samples. If you are in the long booster arm, you will be given the second dose of your assigned COVID-19 vaccine. Following vaccination, we will ask you to remain with us for 20 minutes of observation. If you have been vaccinated at this visit, we will again ask you to complete a daily e-diary for 28 days.

COHORT 2: Visit 5 – Maternal Visit [30 minutes]

This visit will take place 84-122 days after your first vaccination OR 28-42 days after your booster dose if you are in the long interval booster arm, at the trial site. We will review your e-diary if you are in the long interval booster arm and were vaccinated with a COVID-19 vaccine at visit 4, enquire about your

health since your previous visit, perform a brief medical examination (if indicated) and take blood samples.

COHORT 2: Visit 6 – Maternal visit [30 minutes]

This visit will take place 112-140 days after your first vaccination OR 56-84 days after your booster dose if you are in the long interval booster arm. We will enquire about your health since your previous visit, perform a brief examination (if indicated) and take blood samples.

COHORT 2: Visit 7 – Maternal and baby, at delivery

This visit will coincide with your delivery. After delivery, we will take a blood sample from you and an umbilical cord blood sample (to be taken at selected trial sites only). A member of the trial team or a member of the clinical team looking after you at the time may take these samples. If it is not possible to take a blood or cord sample at delivery, we will ask you if we can take a blood sample from you and your baby in the first week following delivery. If you decide to breastfeed your baby and have consented to take part in the sub-study investigating immunity in breast milk after vaccination, we will provide you with information on how to collect a colostrum sample and provide you with containers in preparation to do so.

COHORT 2: Visit 8 – Maternal, after delivery (ONLY if in breast milk sub-study) [30 minutes – 1 hour]

This visit will only occur if you decide to take part in the breast milk sub-study. If so, it will take place 0-7 days after your delivery at home or at the trial site. We will enquire about your health since delivery. If you are taking part in the breast milk sub-study, this visit will take place in the hospital or at your home and we will ask you to provide a 1-2mls sample of colostrum.

COHORT 2: Visit 9 – Maternal, after delivery [Telephone call or 30 minutes if taking place on-site/ home]

This visit will take place 12-16 days after your delivery via telephone. We will enquire about your health since delivery. If you are taking part in the breast milk sub-study, this visit will take place at the trial site or at your home and we will ask you to provide a 2-5mls sample of breast milk.

COHORT 2: Visit 10 – Maternal, after delivery [1 hour]

This visit will take place 28-42 days **OR** 70-84 days after your delivery (decided by randomisation), either at the trial site or at your home. We will enquire about your health and perform a brief medical examination (if indicated). We will also collect a blood sample from your baby (about 1 teaspoonful); an experienced member of the trial team will take this.

COHORT 2: Visit 11 – Maternal, after delivery [Telephone call]

This visit will take place 142-166 days after your delivery via telephone, where we will enquire about your health.

COHORT 2: Visit 12 – Maternal, after delivery [1.5 – 2 hours]

This visit will take place 349-379 days after your delivery, either at the trial site or at your home. We will enquire about your health, perform a brief examination of you if indicated, and collect a blood sample. We will also perform a developmental assessment of your baby using a questionnaire if this has not already been done during their routine healthcare.

Specific trial visits – COHORT 3

Visit Number	Screening + V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12
Study Day	**0**	**10-21**	**28-42**	**No visits in this cohort**			**DELIVERY**	**0-7 after delivery**	**12-16 after delivery**	**28-42 after delivery**	**182 after delivery**	**364 after delivery**
Location	Trial site	Telephone	Trial site				Delivery site	Trial site	Telephone (Home/ trial site if in BM sub-study)	Home/ Trial site	Telephone	Home/ Trial site
Main activities	Consent Screening Examination E-diary set-up	Review	Review				Review	Review	Review	Review	Review	Review Baby assessment
Blood tests	Maternal		Maternal				Cord Blood* Maternal			Maternal Baby		Maternal
Breast milk (BM) collection (optional)								Colostrum*	Breast milk*			
Vaccination	 **Covid-19**							 **Covid-19****				

* Cord blood samples + breast milk samples will be taken at selected sites only; if unable to get cord blood sample, we would ask you whether we may obtain a baby blood sample in the first week instead ** Booster dose will be given as soon as possible after delivery

COHORT 3: Screening + Visit 1 – Maternal Visit [1.5 – 2 hours]

This visit will take place when you are between 28+0 – 34+0 weeks in your pregnancy at the trial site.

At this visit, we will check that you are eligible to be enrolled onto the trial and discuss the trial with you. You will then be asked to sign a consent form. We will collect some demographic details from you including your NHS number, and information about your general health, medication history and your pregnancy. You will then have a brief medical examination, your height and weight checked, and blood tests taken.

You will then be randomly assigned an 'arm' in your cohort. This will determine which COVID-19 vaccine you will receive. This means that the COVID-19 vaccine you will receive in the study will be selected at random; the team will know the vaccine you are given but you will not until the end of the study.

At this visit, you will be then given the 1st dose of the vaccine you are assigned. Vaccination will be done by members of the trial team who are trained and experienced in vaccine administration and in emergency procedures in the event of an allergic reaction. They will have access to emergency medication and equipment. After vaccination, we will ask you to remain with us for 20 minutes of observation and during this time we will show you how to complete an e-diary. We ask that you complete this daily for 28 days following vaccination.

COHORT 3: Visit 2 – Maternal Visit [Telephone call]

This visit will take place 14 (+/- 7) days after your first vaccination via telephone. We will review your e-diary and enquire about your health since your 1st vaccination.

COHORT 3: Visit 3 – Maternal Visit [30 minutes]

This visit will take place 28-42 days after your first vaccination, at the trial site. We will review your e-diary, enquire about your health since your 1st vaccination, perform a brief examination (if indicated) and take blood samples.

COHORT 3: Visits 4, 5 and 6

For Cohort 3, there are no visits 4, 5 and 6.

COHORT 3: Visit 7 – Maternal and baby: At delivery

This visit will coincide with your delivery. After delivery, we will take blood samples and an umbilical cord blood sample (to be taken at selected trial sites only). These samples may be taken by a member of the trial team or a member of the clinical team looking after you at the time. If it is not possible to take a blood or cord sample at delivery, we will ask you if we can take a blood sample from you and your baby in the first week following delivery. If you decide to breastfeed your baby and have consented to take part in the sub-study investigating immunity in breast milk after vaccination, we will provide you with information on how to collect a colostrum sample and provide you with containers in preparation to do so.

COHORT 3: Visit 8 – Maternal: After delivery [1.5 – 2 hours]

This visit will take place 0-72 hours after your delivery. This visit will take place in the hospital. We will enquire about your health since delivery and perform a brief examination. If you have agreed to provide a colostrum sample we will collect a 1-2mls sample of this.

You will then be given the second dose (booster) of your assigned COVID-19 vaccine and we will ask you to complete a daily e-diary for 28 days again. Following vaccination, we will ask you to remain with us for 20 minutes of observation.

COHORT 3: Visit 9 – Maternal, after delivery [Telephone call or 30 minutes if taking place on-site/ home]

This visit will take place 12-16 days after your delivery via telephone. We will enquire about your health since delivery. If you are taking part in the breast milk sub-study, this visit will take place at the trial site or at your home and we will ask you to provide a 2-5mls sample of breast milk.

COHORT 3: Visit 10 – Maternal: After delivery [1 hour]

This visit will take place 28-42 days after your delivery, either at the trial site or at your home. We will enquire about your health and perform a brief examination (if indicated). We will also collect a blood sample from your baby (about 1 teaspoonful); this will be taken by an experienced member of the trial team. We will again review your e-diary with you.

COHORT 3: Visit 11 – Maternal: After delivery [Telephone call]

This visit will take place 142-166 days after your delivery via telephone, where we will enquire about your health.

COHORT 3: Visit 12 – Maternal: After delivery [1.5 – 2 hours]

This visit will take place 349-379 days after your delivery, either at the trial site or at your home. We will enquire about your health, perform a brief examination of you if indicated, and collect a blood sample. We will also perform a developmental assessment of your baby using a questionnaire if this has not already been done during their routine healthcare.

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Specific trial visits – COHORT 4

Pre-trial	Visit Number	Screening[$]	V1[$]	V2	V3	V4	V5	V6	V7	V8[A]	V9	V10	V11	V12
	Study Day		**0**	**10-21**	**28-42**	**No visits in this cohort**		**112-140[¥]**	**DELIVERY**	**0-7 after delivery**	**10-21 after delivery**	**28-42 OR 70-84 after delivery**	**182 after delivery**	**364 after delivery**
	Location	Trial site	Trial site	Telephone	Trial site			Trial site	Delivery site	Visit ONLY if BM sub-study (Home/ trial site)[A]	Telephone (Home/ trial site if in BM sub-study)	Home/ Trial site	Telephone	Telephone (Home/ trial site if in BM sub-study)
	Main activities	Consent Screening Examination	Examination E-diary set-up	Review	Review			Review	Review	Review[A]	Review	Review	Review	Review Baby assessment
	Blood tests		Maternal		Maternal			Maternal	Cord Blood* Maternal			Maternal Baby		Maternal
	Breast milk (BM) collection (optional)									Colostrum*	Breast milk*			
Covid-19	**Vaccination**		**Covid-19**											

* Cord blood samples + breast milk samples will be taken at selected sites only; if unable to get cord blood sample, we would ask you whether we may obtain a baby blood sample in the first week instead; [¥] This visit will only take place if you have not yet delivered

[$] If you are randomised to receive booster dose before 26 weeks in pregnancy, screening and V1 will take place together as a combined visit; if you are randomised to receive booster dose from 26 weeks in pregnancy onwards, then if you are not already at this stage, your V1 visit will only take place once you are at this stage.

[A] You will only have a visit 8 if you decide to take part in the breast milk sub-study

COHORT 4: Screening Visit – Maternal Visit

You will be placed in this cohort if you have already had a first dose of a COVID-19 vaccine before you were pregnant or when in your first trimester (up to 12+6 weeks gestation), as recommended by the Joint Committee on Vaccination and Immunisation (JCVI) in the UK.

This visit will take place when you are between 13+0 – 34+0 weeks in your pregnancy. At this visit, we will check that you are eligible to be enrolled onto the trial and discuss the trial with you. You will then be asked to sign a consent form. We will collect some demographic details from you including your NHS number, and information about your general health, medication history and your pregnancy. You will then have a brief medical examination, and your height and weight checked. You will then be randomly assigned to receive the second dose (i.e. booster) of the COVID-19 vaccine you have already received pre-trial at either before 26 (i.e. up to 25+6) weeks of pregnancy or from 26 weeks and onwards.

COHORT 4: V1 – Maternal Visit

At this visit you will be given the booster dose of your COVID-19 vaccine. Vaccination will be done by members of the trial team who are trained and experienced in vaccine administration and in emergency procedures in the event of an allergic reaction. They will have access to emergency medication and equipment. After vaccination, we will ask you to remain with us for 20 minutes of observation and during this time we will show you how to complete an e-diary. We ask that you complete this daily for 28 days following vaccination.

If you are randomised to receive the booster dose before 26 weeks in pregnancy, screening and V1 will take place together as a combined visit; if you are randomised to receive booster dose from 26 weeks in pregnancy onwards, then if you are not already at this stage, your V1 visit will only take place once you are.

COHORT 4: Visit 2 – Maternal Visit

This visit will take place 10-21 days after your booster vaccination. We will review your e-diary, enquire about your health since your vaccination and take another blood sample.

COHORT 4: Visit 3 – Maternal Visit

This visit will take place 28 days after your booster vaccination. We will review your e-diary, enquire about your health since your vaccination, perform a brief examination (if indicated) and take blood samples.

COHORT 4: Visits 3 and 4

For Cohort 4, there are no visits 3 and 4.

COHORT 4: Visit 6 – Maternal visit

This visit will take place 112-140 days after your booster dose. We will enquire about your health since your previous visit, perform a brief examination (if indicated) and take blood samples.

COHORT 4: Visit 7 – Maternal and baby: At delivery

This visit will coincide with your delivery. After delivery, we will take blood samples and an umbilical cord blood sample (to be taken at selected trial sites only). These samples may be taken by a member of the trial team or a member of the clinical team looking after you at the time. If it is not possible to take a blood or cord sample at delivery, we will ask you if we can take a blood sample from you and

your baby in the first week following delivery. If you decide to breastfeed your baby and have consented to take part in the sub-study investigating immunity in breast milk after vaccination we will provide you with information on how to collect a colostrum sample and provide you with containers in preparation to do so.

COHORT 4: Visit 8 – Maternal: After delivery (ONLY if in breast milk sub-study)

This visit will only occur if you decide to take part in the breast milk sub-study. If so, it will take place 0-7 days after your delivery at home or at the trial site. We will enquire about your health since delivery. If you are taking part in the breast milk sub-study, this visit will take place in the hospital or at your home and we will ask you to provide a 1-2mls sample of colostrum.

COHORT 4: Visit 9 – Maternal: After delivery

This visit will take place 12-16 days after your delivery via telephone. We will enquire about your health since delivery. If you are taking part in the breast milk sub-study, this visit will take place at the trial site or at your home and we will ask you to provide a 2-5mls sample of breast milk.

COHORT 4: Visit 10 – Maternal: After delivery

This visit will take place 28 days **OR** 70-84 days after your delivery (decided by randomisation), either at the trial site or at your home. We will enquire about your health and perform a brief examination (if indicated). We will also collect a blood sample from your baby (about 1 teaspoonful); this will be taken by an experienced member of the trial team.

COHORT 4: Visit 11 – Maternal: After delivery

This visit will take place 142-166 days after your delivery via telephone, where we will enquire about your health.

COHORT 4: Visit 12 – Maternal: After delivery

This visit will take place 349-379 days after your delivery, either at the trial site or at your home. We will enquire about your health, perform a brief examination of you if indicated, and collect a blood sample. We will also perform a developmental assessment of your baby using a questionnaire if this has not already been done during their routine healthcare.

Cord blood sampling

A cord blood sample will be taken following the birth of your baby by the attending midwife or doctor. This sample is taken from the part of the umbilical cord attached to the placenta after the cord has been clamped and cut. This does not hurt you or your baby. Taking a cord blood sample will not affect any requests for delayed cord clamping and will not impact on your ability to bank cord blood if that is something you wish to do. In the unlikely event that we are unable to obtain a cord blood sample we will ask if we can take a blood sample from your baby before they are seven days old.

What happens if I or my baby develop symptoms of COVID-19 during the trial?

You will be sent weekly reminders (either in the form of a text message or email) to immediately contact the trial team if you develop any new symptoms or health concerns that could be suggestive of COVID-19.

If either you or your baby do ever develop symptoms of possible COVID-19 we will ask you to contact the trial team within 24 hours of symptom onset. This will be via a specific on-call phone number for the trial that you will be given which will be available 24 hours 7 days a week. You will then be asked to take a community COVID-19 test for yourself. If you test positive, this will be noted and we will ask you to complete a symptom e-diary for at least 7 days and until symptom resolution. If your baby develops symptoms suggestive of possible COVID-19 infection, we will advise on arranging testing. If your baby tests positive we will ask you to complete a symptom e-diary for at least 7 days and until symptom resolution. We will then also arrange a trial visit to review and examine your baby and take blood samples. If required, further subsequent visits may be arranged.

Blood and breast milk sample results

The trial team will not receive individualised blood sample, cord blood or breast milk sample (if applicable) results, and as such we will not be able to give you any individualised results of samples that we take during the study as part of the planned routine study schedule.

If any safety bloods tests needed to be done e.g. if you or your baby were diagnosed with COVID-19 and were invited for additional visits, then the results of these tests would be provided to you.

COVID-19 precautions

Due to the on-going COVID-19 pandemic Princess Royal Hospital (The Shrewsbury & Telford Hospital NHS Trust) has been treating COVID-19 patients. We are taking extra steps to ensure both staff and participants are kept safe at all times and to prevent any spread of COVID-19. As part of this, you will be asked to follow the hospital policy on social distancing and PPE if you attend the hospital for a trial visit. Staff will be adhering to strict cleanliness guidelines and, in some cases, this may mean full PPE during home visits.

The trial team will contact you ahead of scheduled study visits to check for any COVID-19 symptoms and the symptom check will be repeated at the study visit. If either you or a household member is currently experiencing any COVID-19 symptoms, please do NOT attend for your appointment and contact us to let us know so we can postpone your appointment.

What are the possible benefits of taking part?

By taking part in the trial you would be helping us to understand more about the use of vaccines against COVID-19 in pregnancy - specifically their safety and ability to produce an immune response in pregnant women and their babies, as well as whether different dosing intervals make any difference to these

immune responses. This research will inform the national immunisation programme in the UK on what advice to give to women already pregnant or planning to become pregnant. The final results of the trial will be published in a medical journal and you will be provided with a link to the publications when they become available.

What are the possible disadvantages of taking part?

Blood sampling

This trial involves at least 5 blood tests from you and 1 blood test from your baby and may include up to two samples of breast milk. Blood tests can be uncomfortable and may cause slight pain and/or bruising at the site where the needle enters. Some people feel light-headed or even faint when having blood taken. Blood sampling will be performed by an experienced member of the team and you will be offered a medicated numbing cream for your baby for their blood test.

COVID-19 Vaccination side effects

Common side effects

People very often have tenderness, pain, warmth, redness, itching, swelling or bruising or less commonly have a small lump in their arm at the site that they have been vaccinated.

Other common systemic side effects

Some people can develop these symptoms after vaccination. They usually last for less than a week after you are vaccinated (more commonly 24-48 hours afterwards).

- Fatigue
- Headaches
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- Muscle aches
- Joint aches
- Feeling unwell (malaise)
- Feeling sick or nauseated or vomiting

Other less common side effects:

- Abdominal pain
- Decreased appetite
- Feeling dizzy
- Swollen lymph nodes (glands)
- Excessive sweating, itching skin or rash

These symptoms can be reduced by use of paracetamol around the time of immunisation and over the next 24 hours. We would not routinely recommend the use of ibuprofen or other anti-inflammatory medication at this time.

Serious Reactions

With any vaccination there is a small risk of rare serious adverse events, such as an allergic reaction. Severe allergic reactions to vaccines (anaphylaxis) are rare (approximately 1 per million vaccine doses), but can be fatal. In case of this unlikely event, medication for treating allergic reactions is available and the researchers are appropriately trained in the management of anaphylaxis.

These are new vaccines, and there may be side effects that
we are not yet aware of. Further information about vaccine safety is being actively gathered as the vaccines are being used in the UK and globally. You will be informed of any significant change in the vaccine safety profile.
You will be provided with a 24h trial mobile number. If you experience unexpected events or become in any way concerned you can use this to contact one of the trial doctors at any time. We will ask you to record these symptoms in the e-diary too.

Pertussis (Whooping cough) vaccine side effects

The pertussis vaccine is a very well tolerated vaccine and there are no concerns about the safety of pertussis-containing inactivated vaccines at any stage in pregnancy. As it is an inactivated vaccine, it contains no live organisms, cannot replicate and so cannot cause infection in a mother or her baby.

Common side effects include injection site pain, redness and/or swelling and fatigue. Some people may also have a fever, abdominal pain, vomiting, nausea or headache.

What if I am eligible for routine immunisation against COVID-19, or become eligible whilst enrolled in the trial?

Participation in this trial means that you will be receiving COVID-19 vaccines that are already being administered as part of the national UK programme. It is important to note that participants in this trial will not know which vaccine schedule they have received until after the end of the trial. This procedure is known as blinding and is a critical part of the trial to avoid bias. For example: If you know which vaccine you have, you might, subconsciously be more or less likely to report certain symptoms. For this purpose, we would not unblind you (tell you which vaccines you received) until the end of the trial, even if you withdrew from the trial, as it would seriously affect our ability to interpret the trial data. We would, however, unblind participants if:

- It became apparent that one schedule was producing an immune response that was thought to be inadequate
- There was an urgent safety need

What happens if I change my mind?

If, at any time, after enrolment, you change your mind about being involved with this trial you are free to withdraw without giving a reason. If you withdraw, we would not usually perform any more research procedures; although occasionally we might need to offer you a follow up visit for safety purposes, for example for blood tests. You would not have to agree to this. Your decision will not result in any penalty. Unless you state otherwise, any samples taken whilst you have been in the trial will continue to be stored and used for research as detailed above. You are free to request that your samples are destroyed at any time during or after the trial. Your data would be managed as laid out in the section 'How will my personal data be handled'. If you choose to withdraw from the trial, your standard medical care will not be affected.

What if there is a problem?

St George's, University of London is the study sponsor and is covered by appropriate indemnity. If you are harmed as a result of your participation in the study, you may be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received as part of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action. Where the Trial is conducted in an NHS hospital, the NHS has a duty of care to participants.

What happens when the research stops or if new information becomes available?

Sometimes during a trial, new information relevant to the trial becomes available. If this happens, we will tell you about it and discuss whether you want to, or should, continue in the trial. If you decide to continue to take part, you may be asked to sign an updated consent form. On receiving new information, we may consider it to be in your best interests to withdraw you from the trial. Your participation in this trial may also be stopped at any time by the trial doctor or the Sponsor for other reasons.

What if I wish to make a complaint about the trial?

If you have any concerns about the way you have been treated during this trial or wish to make a complaint, then you can talk to the Preg-COV research team who will do their best to answer your questions or concerns (contact details at the end). Alternatively, you may contact the Patient Advice and Liaison Service:

Shrewsbury & Telford Hospital NHS Trust Patient Advice and Liaison Service (PALS)
Shrewsbury 01743 261000 x 1691
Telford 01952 641222 x 4382
E-mail: sath.pals@nhs.net

The National Health Service complaints mechanisms are also available to you.

How will my personal data be handled?

St George's, University of London (SGUL) is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records, and that of your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. We may keep information collected for the purpose of the study for up to 15 years after the study has finished. This is to ensure integrity of the results. All data will be stored in a secure manner.

Princess Royal Hospital (The Shrewsbury & Telford Hospital NHS Trust) will collect information from you and/or your medical records, and that of your child for this research study in accordance with our

instructions. Princess Royal Hospital (The Shrewsbury & Telford Hospital NHS Trust) will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from SGUL, Princess Royal Hospital (The Shrewsbury & Telford Hospital NHS Trust), UK government and regulatory organisations may look at your medical and research records to check the accuracy of the research study. SGUL, as sponsor, will only receive information without any identifying information. We may share research data collected during this study with government bodies to support the development, promotion or provision of public healthcare. The people who analyse the information will not be able to identify you or your baby and will not be able to find out your or your baby's name, identifying information or contact details.

Princess Royal Hospital (The Shrewsbury & Telford Hospital NHS Trust) will keep identifiable information about you from this study for up to 3 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your research information in specific ways in order for the research to be reliable and accurate. If you withdraw your consent to participate in a research project, this will not mean we will have to remove all data as well. We will keep the information about you that we have already obtained to ensure research integrity is maintained in the public's interest.

You can find out more about how we use your information here:

https://www.sgul.ac.uk/privacy

For general information on how the NHS uses research data please visit:
https://www.hra.nhs.uk/information-about-patients/

What will happen to my samples?

Your trial samples will be analysed in the site laboratories, St George's University of London (SGUL) research laboratories, Public Health England (PHE) laboratories or other specialist laboratories. Other tests to look at the response of your body to the vaccine may also be done with collaborating laboratories in the UK and in other countries, including North America. Any samples or data sent to them would not include information that identifies you.

If you consent, some of your leftover blood samples can be stored and used for future infectious disease or vaccine-related research in the SGUL BioBank. This is optional; your participation in this trial will not be affected by your decision whether to allow storage and future use of your leftover samples. Upon your request at any time, your remaining blood samples will be destroyed.

What will happen to the results of the trial?

Your local trial team will write to you at the end of the trial to inform you of the trial findings. We will retain your contact details in a secure database at the site to enable us to contact you. We plan to

publish the results in a medical journal so that other healthcare professionals can learn about the findings of the study. If you wish, you can also be sent a copy of the published research.

Will I be compensated for taking part in this trial?

Once enrolled you will be compensated for your time, the inconvenience of having blood tests and procedures, and your travel expenses. The total amount compensated will be up to £45 per visit.

Trial reimbursement will be made by bank transfer throughout the trial, so please bring your bank details with you to your screening visit (no cash payments can be made). Should you decide to withdraw from the trial before it is completed, payment will be pro rata (you will receive a proportion of the total amount).

Will I be given proof of immunisation?

At the vaccination visit you will be given a COVID-19 vaccination card or letter, which is the same as that used in the national vaccination program. The difference is, unlike in the national program, this card or letter will not give the name and batch number of the vaccine you have received (as this would unblind you). Instead the card or letter will say “COVID-19 vaccine”. These cards or letters are not at present considered to be "vaccination passports" - and this is true whether you receive them through the national immunisation programme or through a trial. The UK has not, as yet, introduced any kind of official certification system in relation to vaccinations and it is unclear whether they will do so. Until such time as any formal documentation system is implemented and required of people, we won't be supplying anything additional other than the above-described vaccination cards. We will always seek not to disadvantage our participants, and will be responsive to any of these kinds of potential changes - taking advice from the trial oversight committees.

Who is organising and funding the trial?

The trial is organised and sponsored by St George’s, University of London. The trial is funded through financial support to SGUL from the UK Vaccine Taskforce and the National Institute for Health Research (NIHR), which is a UK government funded research agency. Neither your GP nor the researchers are paid for recruiting you into this trial.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the interests of donors/participants. This study has been reviewed and given favourable opinion by North East - Newcastle & North Tyneside 1 Research Ethics Committee, as well as approval by St George’s Joint Research and Enterprise Service.

Taking part in future vaccine-related research

With your consent, we would like to keep your contact details after the trial is complete, so we may inform you of opportunities to participate in future vaccine-related research. This is entirely optional and your participation in this trial will not be affected by your decision to allow or not allow storage of your contact details beyond your participation in this trial.

Your details will be stored electronically on a secure server and only authorised individuals at SGUL will have access to it. We will not, under any circumstances, share your contact details with any third party institutions without your permission. Being contacted does not oblige you to agree to take part in future research and you can ask us to have your contact details removed from our database at any time.

Further information

If you have any questions, or would like further information please contact:

Preg-CoV trial team at
Princess Royal Hospital
Apley Castle
Telford
TF1 6TF
Tel: 01952 641222 ext 5939
Email: helen.millward1@nhs.net

Thank you for taking the time to read this information leaflet. If you have any further questions please do get in touch with a member of the team.