

Quality of Life Effects of Chickenpox on Children and their Families admitted to Hospital



Parent Information Sheet

What is this study about?

Chickenpox is a very common illness that almost all children catch before the age of five. For most it is a short illness with an itchy spotty rash but no long lasting effects, but some children will need admitting to hospital. There are very effective vaccines against chickenpox that are used in many other countries. We don't use them in the UK because we don't have enough information of the effects of having chickenpox on children and their families. This study collects data on children most severely affected by chickenpox to help decide if the vaccine should be used in the future.

Who can be in the study?

We are looking for around 100 children admitted to hospital as a result of having had chickenpox.

What does this research study involve?

It would mean filling in a short questionnaire every day while in hospital and then taking a simple diary card to complete once a week when you are discharged and one final follow up at six months.

A study doctor or nurse will contact you a few times during this to make sure your child is still ok.

Do I have to take part?

You (and your child) do not have to be in this study. If you do decide to take part but change your mind later, you can stop whenever you want without giving a reason.

Does being in this study help my child?

Taking part in this study will not directly benefit you or your child. But it will provide vital information on how chickenpox affects children and their families in the UK and potentially influence the future vaccines other children receive.

Who has reviewed this research?

All research studies must be approved by a special group called a Research Ethics Committee before they can start. This group consists of medical and research experts and ordinary people not involved in medicine or research, none of whom are linked in any way to the teams doing the research. It is their job to protect the rights and well being of the people taking part and make sure that the project comes up to the high standards that are set for research done in the UK. This study has been reviewed and approved by the East of Scotland Research Ethics Service.

Details of the Study

Consent

If you are interested, a study doctor or nurse will talk with you about the study and answer any questions you have. If you still want to help, you will need to sign a short consent form.

Who is organising and funding the research?

The study is run by the University of Bristol. It is funded by money from the National Institute for Health Research with additional funding donated by GSK and Merck.

What will happen to information I provide?

The University of Bristol (UoB) is the sponsor for this study and will act as the data controller responsible for looking after your information and using it properly. All the information you give as part of the study will be treated as confidential and will not be disclosed to anyone outside the research team. Procedures for handling, processing, storage and destruction of your data will be compliant with the Data Protection Act 2018.

Who will have access to my child's study information?

It is very important to us that your details stay absolutely confidential. Your family will be given a special code number to identify them in the trial. Any personal details will only be kept as long as necessary and always be stored locked up or encrypted. The only people with access to personal information will be those caring for your child or running the study. When the results of this study are published no-one will be able to identify your child from them.

Your local site St George's Hospital will record your name and contact details to contact you about the research study, they will keep these confidential and will not pass this information to anyone else. The University of Bristol will only receive results without any identifying information and this will be stored securely at University of Bristol. The people who analyse the data will not be able to identify you and will not be able to find out your name, or contact details.

If your child has developed chickenpox despite being vaccinated we will ask you for your permission to report

that the vaccine didn't work to the appropriate health agencies.

What happens at the end of the study?

When the study is completed all data will be anonymised (names and addresses removed) so that nothing can be traced back to a particular person.

St George's Hospital will keep identifiable information about you from this study for 12 months after the study has finished so that we can send you a copy of the result but you may request these data to be deleted at any time. If you do withdraw from the study, we would like to keep any non-personal study information that you have already given us.

What if you have questions about the study?

With any queries you can always contact the lead research doctor Dr Sabina Ikram:

☎ 0208 725 2780 chickenpoxstudy@sgul.ac.uk

But if you still have concerns about the conduct of the study you can contact either:

The St George's University of London Research Governance Team:

☎ 0208 725 6488 researchgovernance@sgul.ac.uk

The Hospital's NHS Patient Advice Liaison Service (PALS)

☎ 0208 725 2453 pals@stgeorges.nhs.uk