Imperial College London

DIAMONDS MAKING DIAGNOSIS PERSONAL

St George's University Hospitals NHS NHS Foundation Trust

Diagnosis and Management of Febrile Illness using RNA Personalised Molecular Signature Diagnosis

Chief investigator: Prof. Michael Levin
Principal Investigator: Dr Simon Drysdale

DIAMONDS Search Participant information sheet – parents & guardians

Introduction

We are inviting your child to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. This information sheet is for you to keep. If you decide for your child to take part and you sign the consent form, you will also be given a copy of the consent form to keep. Please take your time to read this information sheet and ask us questions if anything is not clear, or if you would like more information. You should only take part in this research study if you want to. Your decision will not affect your child's clinical care.

Why is this research study needed?

Patients come to hospitals every day with common symptoms, such as fever, which suggest that they have a virus or bacterial infection. However, in some cases there may be no infection present, even though the symptoms are similar – for instance in inflammatory illnesses. When different illnesses have similar symptoms, it can be difficult to make a diagnosis accurately and quickly. This means that optimal treatment may be delayed.

What is the aim of the research?

We want to design new diagnostic tests that can tell us quickly and accurately what illness a patient has when they come to hospital with common symptoms such as fever. This would help us give the right treatment to the right patient, at the right time.

Why has my child been chosen and what will happen if my child takes part?

Your child has been chosen as he/she may have an infectious or an inflammatory illness. If the doctors looking after your child plan to carry out blood tests, we would like to take some extra blood for our research at the same time. We may also request to take other samples such as a throat swab, saliva, urine or stool. We might ask for research samples on three separate occasions during your child's time at hospital. If it is not possible to take research blood samples at the same time as clinical samples, we may ask for permission to take research samples on their own.

Children requiring urgent assessment – deferred consent

In order to study children who are unwell, it is important to take our research samples before treatment has started. If your child had a blood test before we had an opportunity to discuss the research with you, we may have kept a small amount of blood sample for this study at the same time. We will only use these samples with your consent. Otherwise we will dispose of them.

Will we ask for any other information?

We want to understand if better diagnostic tests could lead to more efficient use of resources. We may invite you to complete a questionnaire on your experience of seeking medical care for your child's illness, up to the point you came to hospital. Filling in the questionnaire is not compulsory.

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The information you give will not affect any part of your child's medical care. With your permission, after the illness we may send you a follow-up questionnaire about the costs to you and your family that were associated with your child's illness. If you also agree, we will use postcode information to link clinical data to local regions, in order to understand local patterns of disease.

Children who have repeated admissions
If your child comes back to hospital with a new illness with fever or similar symptoms, we would like to record your child's clinical information and take samples for research on those occasions too.

Who else is taking part in the study?
We are part of a research consortium, with hospitals in 11 countries in the UK, Europe, Asia and West Africa. We aim to collect samples from 5000 patients.

What will happen to the blood and other samples?
We will look for infections in throat/nasal swabs and blood using tests that are not routinely available in hospital. We will look at a range of proteins and other molecules from different cell types which might be used in a diagnostic test. In particular we will look at the number and type of RNA molecules made from each gene, and see how these differ in each condition. Samples may be analysed by consortium members in the UK or abroad. All members are governed by local rules and regulations for the ethical conduct of research. The samples will be labelled with a unique study number. They will be kept secure, and will only be released with the agreement of the Consortium to research staff at the time of laboratory analysis. This may include the DIAMONDS study team, or third party service providers such as collaborators, outside organisations such as NHS organisations, universities, or commercial companies involved in health and care research. Otherwise they will be transferred to the Medical University of Graz, Austria, where they will be stored securely in a biobank (Biobank Graz; website:biobank.medunigraz.at).

Generation of genetic sequence data
We will generate genetic sequence data in order to look at the genes used in each patient, as we want to identify factors that influence the body's response to infection. Each person has a unique genetic sequence, and we may find differences that increase the risk of future infectious or inflammatory disease. In that case, your child's clinical care team will contact you to discuss these results. We will not look for, and will not disclose any genetic changes that are not linked to your child's illness. Genetic sequence data will be protected, and will only be available to researchers who have been given approval by the DIAMONDS Scientific Executive and Exploitation Team committee.

What will happen after the study has ended?
Samples are a precious resource for scientists working on infectious diseases, and we would like to keep any samples in the hope that they could be of use in the future for other ethically approved studies run by the DIAMONDS study team or by third party service providers. If any of your child's samples remain at the end of the study, we would like to keep them in the biobank for use in other ethically approved studies, but we will only do this if you agree. If you do not agree we will dispose of them.

What are the advantages and disadvantages to joining the study?
We will not be analysing the clinical information or samples while your child is in hospital, but will be storing them to be analysed later, so the results are not likely to help your child's illness and will not affect your child's clinical care. However, the information gained by the study may help improve the diagnosis and treatment of children in the future. If we find significant results that would influence your child's future care, your child's clinical care team will contact you.

There are no disadvantages to joining the study. The small additional amount of blood and other samples taken should not make a difference to your child's well-being.

What will happen if you wish to withdraw your child from the study?
You may withdraw your child from the study at any time, and you don't have to give a reason and it will not affect the standard of care your child receives. We will keep the samples and data that have already been collected but we will not collect any more.

What will happen to the results of the research study?
We may generate findings that we would like to share with the study participants, or which may lead to new avenues of research. In this case we would like permission to contact you. Results of this research will be published in scientific journals. Details of this will be posted on the project website (www.diamonds2020.eu) and on twitter (@DIAMONDS_2020). If there are any profits from new inventions which arise from the study, they will be shared and fed back into the institutions hosting the research (which may be external non-commercial and commercial organisations). There will not be any financial gain for you or your child from the use of your child's samples. Findings from this study will be used to advise healthcare systems across Europe on the best management of patients with fever or other symptoms.

Who is organising and funding the research?
The research is being co-ordinated by Professor Michael Levin in the Section of Paediatric Infectious Disease at Imperial College London in collaboration with hospitals and scientific institutions in and outside Europe. This study has been reviewed and given approval by the Dulwich Research Ethics Committee. The research is funded by the European Commission.

What are the contact details for the local research team?
The Principal Investigator at Imperial College Healthcare NHS Trust is Dr Jethro Herberg. The local research team can be contacted at Imperial College, Norfolk Place, London W2 1PG; email:imperial.paediatricresearch@nhs.net.

Which data will the NHS hospital Trust share with Imperial College?
The only personal information to be shared with Imperial College will be the date of birth. Imperial College has a secure cloud-based Research Data Storage system which complies with GDPR. Imperial College will ensure that this personal information is kept secure and it will never be published.

Who is responsible for looking after the data?
Imperial College London is the sponsor for this study and will act as the data controller. This means that Imperial College London is responsible for looking after your child's information and using it properly. St George's University Hospitals NHS Foundation Trust will keep your child's personal data for 10 years after the study has finished in relation to data subject consent forms and 10 years after the study has completed in relation to primary research data.

St George's University Hospitals NHS Foundation Trust will need to use information from your child's hospital records for this research project. The information will include your child's, name, date of birth and hospital number. People will use this information to do the research or to check your child's records to make sure that the research is being done properly. People who do not need to know who your child is will not be able to see your child's name or contact details. We will keep all information about your child safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

Your child's research data will have a code number so that no one will be able to identify your child. Any information about your child that leaves the hospital will have your child's name, hospital number or full address removed so that the people who analyse the information will not

be able to identify your child or find out your child's name, hospital number or contact details. Your child's research data information may be sent to countries within and outside our consortium. They must follow our rules about keeping your information safe.

What it the legal basis for using my child's information?
As a university, Imperial College London uses personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, Imperial College London has to ensure that it is in the public interest when personally-identifiable information from people who have agreed to take part in research is used. This means that when you agree to take part in a research study, Imperial College London will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that Imperial College London has to demonstrate that their research serves the interests of society as a whole. Imperial College London does this by following the UK Policy Framework for Health and Social Care Research.

Sharing your child's information with others
For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, Imperial College London will share your child's personal data with certain third parties. Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. Imperial College London only permit them to process your child's personal data for specified purposes and in accordance with our policies.

International Transfer of data
There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a partner in the research consortium or other collaborator). Where this information contains your child's personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your child's personal data is processed.

What are your choices about how your child's information is used?
If you withdraw your child from the study we will keep information about your child that we already have but we will not collect any more information. We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child. If you agree for your child to take part in this study, you will have the option for your child to take part in future research using your child's data saved from this study.

Where you can find out more about how your information is used.
Log onto www.hra.nhs.uk/information-about-patients or ask one of the research team, send an email to the research team imperial.paediatricresearch@nhs.net or ring us on 020 3312 1449.

What if there is a problem?
Imperial College London holds insurance policies which apply to this study. If your child experiences harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If your child is harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way your child has been treated during the course of this study

then you should immediately inform the Principal Investigator *(Dr Simon Drysdale. Email: researchforchildren@sgul.ac.uk.*)

In addition the Patient Advice and Liaison Service (PALS) offers confidential advice, support and information for health-related matters. They can also give you advice on the NHS complaints procedure and how to get independent help if you want to make a complaint. You can find your nearest PALS office on the NHS Choices website or from your GP surgery, hospital or phone NHS 111. If you are still not satisfied with the response, you may contact the Research Governance and Integrity Team (RGIT) at Imperial College. If you incur costs as a result of a complaint, you may have to pay your own costs.

How can you complain about use of your personal data?
If you wish to raise a complaint on how we have handled your child's personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your child's personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Thank you for reading about our study