Mechanisms of Adrenal Insufficiency. Parent of a child healthy volunteer

Please read the information sheet and complete the consent form below.

Many thanks

QMUL Endocrinology Department

Information sheet and consent form for parent/guardian of a child healthy volunteer.
Mechanisms of Adrenal Insufficiency

Study Website : https://www.qmul.ac.uk/adrenal/

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Version 2, 01.07.2022 MREC:

Your child is being invited to take part in a research study. We are asking your permission for your child to take part. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

This study is to find out why the adrenal glands are not working properly in some individuals. The adrenals make important hormones, including cortisol our body's natural stress hormone and hormones that maintain our body's salt balance. Adrenal insufficiency is a condition that arises when the adrenal glands are not working properly. While we can usually treat adrenal insufficiency, we are always looking to find better and more convenient types of treatment. The best way to find such new treatments is to understand better how the disease starts in the first place and how it progresses, and we are actively involved in researching adrenal diseases.

This study aims to identify biomarkers which play a part in the development and progression of adrenal gland insufficiency and conditions associated with adrenal insufficiency. We will look at information from blood, hair, saliva, faeces and urine to understand better why the adrenal glands stop working.

Why has my child been invited to participate?

To better understand why the adrenal glands don't work in some children and young people we need to compare information from blood, hair, saliva, urine and faeces with healthy individuals.
Your child has been chosen because he/she is the same age as a patient recruited to our study with adrenal insufficiency or another condition which can also be associated with the development of adrenal insufficiency. Comparing patient samples with those from healthy individuals will allow us to better understand why the disease develops in affected individuals and may also help us establish disease markers for diagnosis and to track treatment.

Does my child have to take part?

It is up to you and your child to decide whether or not to take part, and participation in this study is completely voluntary. We will ask your child's agreement as well if he/she is over the age of six. If both of you do agree to take part you will be given this information sheet to keep together with a copy of the signed consent form. You are under no obligation to participate in this study, and you may withdraw at any time.

What will happen if my child takes part?

At the visit, you and your child will meet a doctor or nurse who will ask you some questions about your child's health. The doctor or nurse will then measure your child's weight and height.
We would like to take 2 samples of blood (about a tablespoonful in total), a urine sample, a faeces sample, saliva sample and a hair sample to compare with samples from an affected patient to see whether there are any chemical changes that can tell us more about the condition.
The samples that we would like to take will depend on the type of adrenal insufficiency of the matched patient. You will be able to consent/ decline each type of sample specified.
The visit will take about one hour. You or another responsible adult can stay with your child at all times to support them.

Is there any benefit to my child taking part?

There will be no benefit directly for your child. However, the samples given will play an important role in our overall understanding of adrenal disease. The information from the study may also help us establish disease markers to be used to aid diagnosis and treatment of these conditions.

What are the risks of taking part?

A stinging sensation may be felt when having the blood test. To minimise this, we would use numbing cream or spray. Occasionally a small bruise may develop. If you feel at any point during the procedure the perceived pain or anxiety is too great for your child please let the doctor/ nurse know.

Expenses and payments

We will reimburse travel and parking expenses incurred for attending the study. We will pay a standard rate (plus parking to a maximum £40) or public transport (maximum £40). We would also like to offer a £20 high street shopping voucher to thank your child for taking the time and effort participating in the study.

How will we use information about your child?

All information which is collected about your child during the course of the research will be kept strictly confidential. All the data will be kept in a database for research purposes; this will be kept in a locked room and accessible only via strict password protection and therefore kept strictly confidential. If you consent for your child to take part in the research the people conducting the study will abide by GDPR, and the rights you have under this. Professor Louise Metherell and responsible individuals from Queen Mary University of London may have access to personal information and data collected during the study. We may also share data with our collaborators but the data will be anonymised and your child's name will not appear on any data sent abroad.
We will need to use information from you for this research project.
This information will include Name / Date of Birth / Information about your child's medical history. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your child's name or contact details. The data will have a code number instead.
We will keep all information 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 you took part in the study.

What will be done with the information and samples used in the research?

All information and samples which are collected during the course of this research will be analysed to gain further information about adrenal disease. The samples and the data will be stored securely, with access only for the study researchers.
We will use the blood, urine, saliva, faeces and hair samples for hormone measurement, to measure aspects of metabolism and to look at RNA (Ribonucleic acid) molecules. In some circumstances we will use cells found in the urine to establish disease models in the lab.

What happens if there is a problem?

Complaints:
If you have any concerns about any aspect of the study you can ask to speak to the researchers who will endeavour to address these, details below.

You can also contact Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone 020 7377 6335, minicom 020 7943 1350, or email pals@bartsandthelondon.nhs.uk, you can also visit PALS by asking at any hospital reception.

Harm:
Queen Mary University of London has agreed that if your child is harmed as a result of his/her participation in the study, your child will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the procedures you received during the course 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 child's right to pursue a claim through legal action.

Who is funding the research?

Research is being coordinated by the team at Queen Mary University of London. Funding is being sought from proprietary clinical and scientific organisations.

Who has reviewed the research?

The study has been approved by a Research Ethics Committee.

What will happen to the results of this study?

The results of this research will be presented at national and international scientific meetings and published in peer review journals. With your consent, we will inform you when the results will be published and how you can obtain copies of the papers. We will also aim to communicate our results through other online platforms including our research site https://www.qmul.ac.uk/adrenal/.

What are your choices about how your child's information is used, what to do if you want to withdraw your child from the study and contact details.

Your child can stop being part of the study at any time, without giving a reason. If you wish to withdraw them from the study please contact the CI - Prof Lou Metherell. Please state if you wish to withdraw and leave the samples and clinical information they have given so far for continued analysis or if you wish to withdraw and have the samples and data destroyed. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study if you decide to say yes to this the samples will be kept at Queen Mary University London, Department of Endocrinology, Chief Investigator - Professor Louise Metherell .
You can find out more about how we use your child's information at www.hra.nhs.uk/information-about-patients/, by asking one of the research team or the data protection officer (data-protection@qmul.ac.uk).
If you have any questions please contact us at bartshealth.adrenal@nhs.net
The Chief Investigator: Prof. Louise Metherell
Consultant Paediatricians: Dr Rathi Prasad and Dr Li Chan
Study Coordinator: Dr Charlotte Hall

CONSENT FORM FOR PARENT/GUARDIAN OF CHILD HEALTHY VOLUNTEER
(Version 02 Dated 01.07.2022)

PLEASE INDICATE AGREEMENT BY SELECTING "I AGREE" OR REFUSAL BY SELECTING "I DO NOT AGREE". YOU MAY INDICATE AGREEMENT TO SOME SECTIONS AND REFUSAL TO SOME OTHER SECTIONS AND YOUR CHILD CAN STILL PARTICIPATE IN THE STUDY.

I confirm that I have read and understand the latest version of the information sheet (version number 02, date of version 01/07/2022) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

◯ I agree ◯ I do not agree

I understand that my participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child's medical care or legal rights being affected. I also understand that if my child clearly does not agree with taking part, having understood the purpose of the study, the research team will not proceed with the investigations.

◯ I agree ◯ I do not agree

I understand that the results of the research will not be made available to anyone, including me or my child, on an individual basis; I also understand that the research will not directly benefit my child's health.

◯ I agree ◯ I do not agree

I agree to my child's GP being informed of my participation in the study.

◯ I agree ◯ I do not agree

I agree to my child having a small blood sample taken for DNA to be extracted. I understand that their DNA (genetic material) may be analysed using modern techniques that are able to analyse all the genes simultaneously (such as next generation sequencing)

◯ I agree ◯ I do not agree

I agree to my child giving a saliva / hair / faeces / urine sample for biochemical analysis

◯ I agree ◯ I do not agree

YOU MUST AGREE TO THE FOLLOWING QUESTION FOR YOUR CHILD TO TAKE PART IN THE STUDY.

I agree that my child can take part in the above study.

◯ I agree ◯ I do not agree

Name of child: _____

Name of parent consenting: _____

Patient date of birth: _____
(Date of birth (day, month, year))

Signature of parent/guardian:

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

Date of signature:

_____
(Date of participant Signature)

Consent obtained by (please enter full name and title):

_____

Signature of person taking consent:

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

Date and Time:

_____
(Date and time of staff signature.)

CONSENT TO DONATION AND STORAGE OF RESIDUAL TISSUE, BLOOD OR OTHER SAMPLES FOR MEDICAL RESEARCH
(Version 2 Dated 01.07.2022)

Following the present research project, any residual (left-over) samples (including but not limited to tissue from blood, hair, saliva, faeces, urine) may be collected, stored and used by the Barts and the London NHS Trust and / or Queen Mary University of London, for medical research in the future. Any future studies will have been independently reviewed by an ethics committee. Research conducted on these samples may contain personal information but all such information will be anonymised at the end of any project, when the results are published, and you will not receive the results of any future research project. All staff undertaking future studies will abide by the General Data Protection Regulation (GDPR) (EU) 2016/679 with any medical information relating to you being kept confidential. The sample may be given to external research organisations for approved medical research but tissue will not be sold, although costs will be recovered without any financial benefit to either you or to the researcher. Any residual tissue will be disposed of lawfully when it is no longer required.

I understand that I have given my consent voluntarily to the storage of my child's samples taken for the above study for future medical research and that I am free to withdraw my consent at any time.

◯ I agree ◯ I do not agree

If you have any preferences or exclusions for use of the donated samples, or any other comments, please include them here:

_____

Name of patient:

_____
(First, Last)

Signature of parent/guardian:	_____ (Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)
Date of signature:	_____ (Date of participant Signature)
Signature of person taking consent:	_____ (Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)
Consent obtained by (please enter full name and title):	_____
Date and Time:	_____ (Date and time of staff signature.)