Mechanisms of Adrenal Insufficiency. Healthy Volunteer Adult

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

Many thanks

QMUL Endocrinology Department

Information sheet and consent form for Adult healthy volunteers.
Mechanisms of Adrenal Insufficiency

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

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Version 2, 01.07.2022 MREC:

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve. Please read the following information carefully, discuss it with others and ask us if anything is not clear.

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 and urine to understand better why the adrenal glands stop working.

Why have I been chosen?

To better understand why the adrenal glands don't work in some people we need to compare information from blood, hair, saliva and urine with healthy individuals.
We are asking you to join the study because you are the same age as a patient in our study who does have adrenal disease.
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.

Do I have to take part?

It is up to you to decide whether or not to take part, and participation in this study is completely voluntary. If 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 without it affecting your normal care in any way.

What will happen if I take part?

We will ask you some questions about your health. We will do this at a time that is ok for you. We will also ask you to give a blood sample, about a tablespoon (15 mls). You do not have to give any blood if you do not want to. We will also ask for a small hair, saliva, faeces and urine sample. 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.

Is there any benefit to taking part?

There will be no direct benefit for you. 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 spray. Occasionally a small bruise may develop.

Expenses and payments

We will reimburse travel and parking expenses incurred for attending the study. We will pay a standard rate (45p 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 you for taking the time and effort participating 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 you 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 right to pursue a claim through legal action.

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/.

How will we use information about you?

All information which is collected about you 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 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 your personal information and data collected during the study. We may also share data with our collaborators but the data will be anonymised and your 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 your Name / Date of Birth / Information about your 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 name or contact details. Your data will have a code number instead.
We will keep all information about you 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.

Who has reviewed the study?

The study has been approved by an Ethics Committee.

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.

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

You can stop being part of the study at any time, without giving a reason. If you wish to withdraw from the study please contact the CI - Prof Lou Metherell. Please state if you wish to withdraw and leave the samples and clinical information you have given so far for continued analysis or if you wish to withdraw and have your 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 your 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 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 HEALTHY ADULT VOLUNTEER (Version 2 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 STILL PARTICIPATE IN THE STUDY.

I confirm that I have read and understand the latest version of the information sheet (version number 2, 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 at any time, without giving any reason, without my medical care or legal rights being affected.

◯ I agree ◯ I do not agree

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

◯ I agree ◯ I do not agree

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

◯ I agree ◯ I do not agree

I agree to give blood for the study.

◯ I agree ◯ I do not agree

I agree to give saliva / hair / urine / faeces for the study.

◯ I agree ◯ I do not agree

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

I agree to take part in the above study.

◯ I agree ◯ I do not agree

Name of patient:

_____

Patient date of birth:

_____
(Date of birth (day, month, year))

Signature of patient:

_____
(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 blood, hair, saliva, feaces, 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 tissue and blood sample for future medical research and that I am free to withdraw my consent at any time.

◯ I agree ◯ I do not agree

I agree that the tissue may be used for future genetic research but not for research that involves reproductive cloning, or to be tested for inherited diseases without my express consent

◯ I agree ◯ I do not agree

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

_____

Name of patient:

_____
(First, Last)

Signature of patient:

_____
(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.)