Imperial College London

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INFORMATION SHEET FOR RESEARCH PARTICIPANTS

You will be given a copy of this information sheet and a signed copy of your consent form to keep, should you decide to participate in the study.

Hydrocortisone versus Prednisolone for Treatment of Adrenal Insufficiency Disease (HYPER-AID Study)

You are being invited to take part in a research study. 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 friends, relatives and your GP 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.

If you do decide to take part, please let us know beforehand if you have been involved in any other study during the last year. You are free to withdraw at any time without explanation. Please be assured that if you decide not to take part this will not affect your clinical care in any way.

Thank you for reading this document.

WHAT IS THE PURPOSE OF THE STUDY?

Currently, the majority of patients with adrenal insufficiency (AI) who need to take steroid replacement are given hydrocortisone tablets three times a day. Prednisolone is an alternative steroid that can be given once daily and is currently already taken by some patients. We would like to compare how patients feel whilst taking prednisolone with when they are taking hydrocortisone. We would also like to investigate whether there are any additional advantages or adverse side effects from taking either medication, particularly looking at the chances of developing heart disease or thin bones (osteoporosis).

This study involves collecting your data before and after you change your therapy from one treatment to the alternative treatment.

Over the course of the study, you will attend your normal clinic appointments, have your usual blood tests and have your weight, heart rate and blood pressure measured and be assessed on how you feel on your medication. After you complete your normal appointments, your data will be collected and compared to how you do on the alternative treatment and to other people who are also changing their treatment. This study will not change or affect any aspect of your usual treatment.

We hope to use the information from the study to help us improve patient care for everyone with adrenal insufficiency.

WHY HAVE I BEEN CHOSEN?

We have asked you to take part in this study because you are changing your steroid regimen as part of your care, from prednisolone to hydrocortisone or from hydrocortisone to prednisolone.

We are recruiting:

- patients who do not produce enough cortisol hormone in their adrenal glands, either because their pituitary or their adrenals don't work.
- patients that are changing between treatments as part of their routine care
- individuals between the ages of 18 and 85.

- patients who have been diagnosed with adrenal insufficiency (AI) for over 6 months
- patients established on stable hydrocortisone or prednisolone replacement, with the dose not altered for at least 4 months
- individuals taking other hormone replacements are accepted providing that their replacement doses have not altered for at least 3 months;

You should not take part in this study if you:

1) are unable to give informed consent
2) are pregnant or using the combined oral contraceptive pill

DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you agree to volunteer for this study we will explain the study in full detail to you and ask you to sign a consent form.

You will need to attend your endocrine clinic appointments as usual. There will be no other change in the way that you are treated, and no additional tests will be done as part of this study. The data for this study will be collected after you have completed your normal clinic appointments. Data will be collected from your first clinic appointment before you change your treatment from hydrocortisone to prednisolone (or vice versa), and the next clinic appointment which is greater than 4 months after you have changed over. You can expect to experience the usual events that occur during your clinic appointments.

During your Clinic Visits you can expect the usual events that occur as outlined below:

Clinic Visit 1 (this will be your normal outpatient appointment).

You will attend Clinic Visit 1 having been on a fixed dose of either prednisolone or hydrocortisone (whichever is your usual therapy) for a minimum of 4 months.

You will arrive at the outpatient department at your appointment time. You will have taken your morning medication. A doctor will explain the study to you and ask you to sign a consent form. There will be no additional study specific events and your care will be no different than usual. As usual we will:

- Measure your weight, height, blood pressure, pulse hip circumference and waist circumference
- Take a blood sample for blood tests (as usual)
- Ask you to provide a urine sample
- Ask you to complete an online questionnaire about your wellbeing

During the appointment you will at some point be given a prescription for the alternative steroid replacement therapy by your doctor (prednisolone if you are usually on hydrocortisone or hydrocortisone if you are usually on prednisolone).

You will take the new treatment until the next Clinic Visit. In order to ensure that you receive the correct dose of the new treatment, you may be contacted on the phone and asked to attend blood tests in the outpatient phlebotomy department. This will be the same as the usual care you can expect to receive outside of this research study.

You will complete the same online questionnaire about your wellbeing every 4 weeks so that we can monitor your health and progress.

Clinic Visit 2

Clinic Visit 2 will be the next outpatient clinic appointment that you attend after you have been taking the new steroid treatment for at least 4 months.

The schedule for the day is the same as any of your usual endocrine clinic appointments and can be found in the section, Clinic Visit 1. There are no study-specific events on this day.

Your information from the two Clinic Visits will be compared with one another and with the information gathered from other people on the study.

WHAT DO I HAVE TO DO?

You will be expected to take your steroid hormone replacement as prescribed.

If you become pregnant during the research, we will ask you to withdraw for the study but will still analyse your data separately. Your clinical care will not otherwise be affected.

WHAT ARE WE TESTING?

We are comparing hydrocortisone and prednisolone to see if there are any differences between the treatments in terms of patient wellbeing, heart disease and bone health. The blood and urine tests are the usual tests that are performed whenever you are seen in clinic.

WHAT ARE THE SIDE EFFECTS OF TAKING PART?

There are no side effects related to this study as it will not change or affect your treatment.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Other than the additional time you will spend with us at your first Clinic Visit to discuss the study and complete the consent form, there are no disadvantages or risks associated with taking part. This study will not change your treatment and will only collect data after your usual appointments.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The information that we get from this study may help us to understand better how to treat future patients who do not produce enough steroid naturally. You will not benefit directly from participating in the study.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor either write to you or will tell you about it during your next appointment.

WHAT WOULD HAPPEN IF I WISH TO WITHDRAW DURING THE COURSE OF THE STUDY?

In the event that you no longer wish to participate, the research team will withdraw you from the study and not collect any further data from your notes. Your decision to withdraw will not affect any other medical treatment that you may receive. The research team would retain personal data collected previously and would continue to use it for the purposes which you had already consented.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

Once the study has finished, the results of the study can be made available to you should you wish. If you have any problems immediately following the study, then you should contact one of the research doctors on the numbers provided below.

WHAT HAPPENS TO MY DATA AND SAMPLES AFTER THE STUDY?

After the study has finished, the personal data you have provided will be securely stored at Imperial College for 10 years. Anonymised data may be securely stored for an indefinite period and may be used for further ethically approved health related research. All information collected about you will remain strictly confidential.

WHAT IF SOMETHING GOES WRONG?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are 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 you have been treated during the course of this study then you should immediately inform the investigators (Professor Meeran, Professor Tan or Dr Choudhury contacted via the hospital switchboard on 020 8383 1000). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. The NHS and Imperial College London as sponsor may also review records as part of our audit process but all information will be kept strictly confidential.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results are likely to be published in the six months following the completion of the study. Your confidentiality will be ensured at all times and you will not be identified in any publication. At the end of the study, the results can be made available to you should you wish.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study is being organised by the Department of Investigative Medicine, Imperial College London. There is no external funding required for this study.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

CONTACT FOR FURTHER INFORMATION

If you experience any problems during the study, you may withdraw at any stage. The hospital switchboard (020 8383 1000) will provide you with access to one of the study doctors during office hours. In the case of an emergency, you should attend your local accident and emergency department.

If you wish to obtain research independent advice or to provide feedback on the study, you can contact: the Patient Advice and Liaison Service (PALS), Ground floor, Charing Cross Hospital, Fulham Place Road, London W6 8RF. Alternatively, you can call them on: 020 3313 0088

TRANSPARENCY STATEMENT

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records 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. Imperial College London will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Principal Investigator on 0207 594 9048, or emailing steroids@imperial.ac.uk.

Imperial College London will collect information about you for this research study from Imperial College Healthcare NHS Trust. Imperial College Healthcare NHS Trust will not provide any identifying information about you to Imperial College London. We will use this information to compare the two major treatments used in adrenal insufficiency to improve care for everyone with the condition..

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.