The STARRY Study 2

A pilot study of **S**alivary cor**T**isol and cortisone concentrations in women and girls with Turner Syndrome **A**nd unaffected female **R**elatives: Associations with cardiovascula**R** and ps**Y**chological health

INFORMATION LEAFLET FOR ADULT PARTICIPANTS AGED 18+ YEARS

You are being invited to take part in a research study. Before deciding whether you wish to take part, 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. Ask us if there is anything that is not clear or if you would like more information.

What is this study about?

Recent research has found that women who have Turner Syndrome might have higher levels of cortisol than women who do not have Turner Syndrome. This may be important, as high cortisol levels increase the risk of developing high blood pressure, high glucose (sugar) levels, and over many years, heart disease. High cortisol levels also make it difficult to maintain a healthy weight.

We would like to learn more about cortisol levels in girls and women with Turner Syndrome, and whether they differ from levels in girls and women without Turner Syndrome. We also want to see if high cortisol levels affect the health of girls and women with Turner Syndrome. It will take a large research study for us to gain this knowledge, and this is the first step in that research plan. If you join this study, you will be helping us to plan our research studies of the future.

What is cortisol?

Cortisol is a hormone (a chemical messenger in the blood) that has many essential functions in our body. It is one of our energy hormones and helps us to fight infection and recover from injuries. Cortisol also helps to control our blood pressure and metabolism (how we store and use fat, protein, and carbohydrates for energy), and we know cortisol is also very important for our cardiovascular health (the health of our heart and blood vessels).

We can detect the levels of cortisol, and an inactive hormone which is very similar to cortisol called cortisone, in your blood and saliva.

Why have I been chosen?

You have been invited to join this study either because you have Turner Syndrome, or you do not have Turner Syndrome but are attending the annual Turner Syndrome Society meeting. All females attending the annual Turner Syndrome Society meeting will be invited to join the study.

What will happen if I agree to take part?

We will be recruiting girls and women into the study at the annual Turner Syndrome Society meeting. At the beginning of the meeting we will:

- Record your current height and weight.
- Measure your body composition. This describes the balance between fat and muscle.
- Ask you information about other medical conditions that you might have. It will be helpful if you could bring information about your medical history and medication to the meeting.

- Ask you to complete a short questionnaire that looks at quality of life. This will take no more than 10-15 minutes to complete. You can complete this questionnaire in the privacy of your room if you prefer and return it to us in a sealed envelope.
- Ask you to collect saliva (spit) samples, and we will show you how to do this. We will give you kits to provide saliva samples either during the conference or at a later date at home. We will ask you to take the samples at 30 minutes 8.5 hours and 16.5 hours after waking. You can set an alarm on your phone to remind you to collect your samples. We will ask you to note in a paper diary (provided) at what time you take the samples. It is important that you rinse your mouth with water before collecting the samples, and do not eat or brush your teeth for 1 hour before you collect a saliva sample. We will measure cortisol and cortisone levels in these samples. If you chose to take your samples at home, you can post them back to us at Alder Hey in a prepaid envelope.

What are the benefits of me taking part in this study?

We might find changes in your cortisol levels that may affect your health in years to come, although we think this is unlikely.

If we find that your blood pressure is higher than it should be, we will let you know what the readings are. We'll ask you to share this information with your GP.

If you prefer, and you're happy for us to do so, we can contact your GP or hospital doctor directly and ask them to follow this up with you.

Are there any risks to me if I join the study?

Blood pressure monitoring and taking salivary samples are safe procedures with no side effects. Some people may find the blood pressure monitor uncomfortable.

Do I have to take part, and can I change my mind?

If you do not wish to take part in the study, you do not have to give a reason. If at any point you wish to withdraw from the study, that is not a problem and you do not have to offer a reason.

What will happen to my information?

In this research study we will use information that you give us about your medical history and medications. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it and to support further research. We will keep this data for 10 years. We will make sure no-one can work out who you are from the reports we write.

How will we (Alder Hey Clinical Research Team) use information about you?

We will need to use information from you for this research project. This information will include your name, date of birth, contact details and GP details. People will use this information to do the research 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 confidential way so that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason.
- We need to manage your 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 you,
- 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. You can stop being part of the study at any time, without giving a reason.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by asking a member of the research team.

What will happen to my salivary samples?

The results of these samples will be recorded. The samples will be link-anonymised and securely stored at Alder Hey for 5 years. The samples will be stored at Alder Hey for 5 years. Only research staff and biochemist staff who are analysing the results will have access to these samples. You may withdraw your consent for the use of your samples at any time. If you do so, any remaining samples will be securely destroyed.

What will happen at the end of the research study?

The results of the study will be analysed and shared with doctors across the world who care for children, young people and adults with Turner Syndrome. The researchers will publish the results in medical journals and present it at medical conferences. Any results that have an impact on you will be communicated by the researchers to you and your GP.

Who is doing this research study?

The study is being performed at the annual Turner Syndrome Society meeting. It has been organised by Alder Hey Children's Hospital, University of Liverpool, Liverpool Centre for Cardiovascular Science and Liverpool Women's Hospital. This research has been approved by a Research Ethics Committee, who has agreed the study is being conducted in an appropriate manner.

What if there is a problem?

If you have any questions or concerns relating to the study, please contact Professor Jo Blair who is leading the study. If you have any questions about your rights in this study, please contact the Patient Advisory Liaison Service (PALS) at Alder Hey.

Thank you for reading this. Please ask us any questions that you have about the study.

Contact details:

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Patient Advice and Liaison Service (PALS)
Alder Hey Children's NHS Foundation Trust, Eaton Road, Liverpool L12 2AP
Telephone: 0151 252 5374 or 0151 282 4907
Or complete an on-line form:
https://alderhey.nhs.uk/parents-and-patients/feedback/pals