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 PARENT/CARERS

You and your child 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 there is any evidence that this causes them health problems. 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 by telling us what you think about the tests that we do, how we do them and how the project could be improved. This will make it much more likely that the study will succeed in 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 has my child been chosen?

Your child has been invited to join this study either because they have Turner Syndrome, or they do not have Turner Syndrome but are attending the annual Turner Syndrome Society meeting. All girls and ladies attending the annual Turner Syndrome Society meeting will be invited to join the study.

What will happen if my child and I agree to take part?

We will be recruiting girls and women into the study at the annual Turner Syndrome Society meeting. The study will take place in a private room at the conference centre, so everything will be quiet and confidential.

If you and your child decide to take part, here's what will happen:

- We will record your child's current height and weight.
- Measure your child's body composition. This describes the balance between fat and muscle.

- Ask you and your child for information about other medical conditions that your child might have. It will be helpful if you could bring information about your child's medical history and medication to the meeting. If you are unsure about this, with your permission, we can contact your child's GP.
- Ask your child to collect three saliva (spit) samples, and we will show them 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 your child to take the samples at 30 minutes, 8.5 hours and 16.5 hours after waking. If the third sample is after their bedtime, then we ask that they take the sample just before going to bed. We encourage you to set an alarm on your phone to remind you and your child to collect the samples. We will ask you to note in the paper diary (provided) at what time you take the samples. It is important that your child rinses their mouth with water before collecting the samples and does not eat or brush their teeth for 1 hour before collecting a saliva sample. We will measure cortisol and cortisone levels in these samples. If you and your child 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 to my child taking part in this study?

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

If we find that your child's 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 child's GP.

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

Are there any risks to my child if they join the study?

Blood pressure monitoring is safe with no side effects, but your child may find the blood pressure cuff a bit uncomfortable. Collecting a saliva sample is also safe, with no side effects, but they might find it a bit unusual at first.

Does my child have to take part, and can we change our mind?

If you do not wish your child to take part in the study, you do not have to give a reason. Your child will still receive the best available care from their treating team. If at any point you wish to withdraw you do not have to offer a reason and the assurance of receiving the best possible care available still applies.

What will happen to my child's information?

In this research study we will use information from you and, with your permission, your child's medical records via their GP/hospital doctor. We will only use information that we need for the research study. We will let very few people know your child's name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your child's 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 your child?

We will need to use information from you and, with your permission, your child's medical records for this research project. This information will include their name, date of birth, NHS number and contact details. 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 their name or contact details. Their data will have a code number instead. 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 you took part in the study.

What are your choices about how your information is used?

- You and your child can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
- 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, or your child see or change the data we hold about them.
- If you and your child agree to take part in this study, your child will have the option to take part in future research using your child's data saved from this study. You and your child can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

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

You can find out more about how we use your information at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/ or by asking a member of the research team.

What will happen to my child's 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. Only research staff and biochemist staff who are analysing the results will have access to these samples. Anonymised samples will be considered a gift to Alder Hey for use in potential future research. We would ask the ethics committee for permission before using the sample again. You may withdraw your consent for the use of your child's 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 girls and women with Turner Syndrome. The researchers will publish the results in medical journals and present it at medical conferences. The study findings will also be shared via the Turner Syndrome Support Society Newsletter and presented at the next Turner Syndrome Support Society Annual Conference.

Who is doing this research study?

The study is being run by doctors and scientists at Alder Hey Children's Hospital, Liverpool Women's Hospital, Liverpool Centre of Cardiovascular Science and the University of Liverpool. 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 about the study, please contact Professor Joanne Blair who is leading the study. If you have any questions concerning your rights in this research study, you may contact the Patient Advisory Liaison Service (PALS) at Alder Hey Children's hospital.

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

Contact details:

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Alder Hey Children's NHS Foundation Trust, Eaton Road, Liverpool L12 2AP

Telephone: 0151 252 55161

Or complete an on-line form:

https://www.alderhey.nhs.uk/visiting/feedback/pals/