



The ST RRY 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 cardiovascular**R** and ps**Y**chological health

INFORMATION LEAFLET FOR YOUNG PEOPLE AGED 13-15 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.

What is this study about?

This study is for girls and ladies who have Turner Syndrome. It will help us to learn what girls with Turner Syndrome and their families or carers think about a future research study that we would like to do. It is important that we do this so that we can plan the best way to do our research. We would like to do a future study to learn more about cortisol levels and the health of girls and ladies with Turner Syndrome.

We think that cortisol might be higher in girls and ladies with Turner Syndrome than in girls and ladies that don't have Turner Syndrome. This would make them more likely to have health problems such as high blood pressure and high cholesterol levels. It might also make it harder for them to stay slim. Learning more about cortisol levels in girls with Turner Syndrome, might help us to understand more about the best ways to help these girls stay fit and healthy throughout their lives.

In this study, we will collect very helpful information about cortisol levels and the health of girls and ladies with Turner Syndrome, but we will need to do another study with many more girls and ladies, to be confident whether cortisol levels are high, and how this might affect people with Turner Syndrome. If you decide to join this study, you will help us to plan the best way to do this research 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 important for:

- Energy throughout the day
- Fighting infection
- Controlling our sugar (glucose) levels
- Helping to control our blood pressure
- The health of our heart and blood vessels

If cortisol levels are high, we think that girls and ladies might be at risk of developing changes in their heart and blood vessels, to gain weight more easily and to have higher sugar levels in their blood. In our future research we would like to see whether this is correct, so that we can improve the treatment of girls and ladies with Turner Syndrome.

Why have you 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 girls and ladies attending the annual Turner Syndrome Society meeting will be invited to join the study.



What will happen if I agree to take part?

While you're at the Turner Syndrome Support Society Annual Conference, we'd like to invite you to take part in our research study. The study will take place in a private room at the conference centre, so everything will be quiet and confidential.

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

- We will ask you a few questions about your general health and any medicines you take. If you're not sure about something, your parents or carers can help. And if they don't know the answer either, with your permission, we can contact your GP.
- We will record your current weight and height and measure your body composition (the balance between fat and muscle on your body) on special weighing scales.
- You may have had your blood pressure checked at the doctors before. As part of this study, we'd like to measure it too. A soft cuff will be placed around your upper arm and will gently tighten for a few seconds to take the reading. We would like to take three readings in total.
- Finally, we will ask you to provide three spit (saliva) samples on one day, either at home or while you are still at the conference. We will show you how to do this. We would like you to collect these samples at the following times: 30 minutes, 8.5 hours and 16.5 hours after waking. On the day that you choose to collect these samples, we recommend that you set timers on your phone to help remind you when to take the samples.

We will give you a Saliva Sample Logbook with instructions for you and your parent/carer(s) as a reminder of how to collect your samples and how to store them. It is important that you rise your mouth with water before collecting a



saliva sample and do not eat or brush your teeth for 1 hour before saliva sample collection (this will affect our results). If you choose to collect your samples at home, we will give you a stamped addressed envelope to send your samples back to us at Alder Hey. If you choose to collect your samples at the conference, we can collect them from you there.

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

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.

What will happen to my information?

All information will be kept private, confidential, and secure. Only people involved in this study or in making sure that it runs correctly will be able to look at your records. Your data will be kept for 10 years after the study. Information may be used in medical journals or presentations. Your name and any other information which means that people can tell it is you will be removed.

Are there any risks if I join the study?

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



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. You will still receive the best available care from your 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.

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, the University of Liverpool and Liverpool Centre for Cardiovascular Science.

Who has reviewed this study?

Before any research can start it is checked to protect you. This has been done by a Research Ethics Committee.

Who can I ask about this?

Your parents or care givers have been given lots of information. If they are not sure, the doctor who gave you this leaflet can tell you more. Please ask if you would like any further information.