Turner syndrome minipuberty study

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The hormonal range of LH, FSH, AMH, inhibin B, testosterone and estradiol in girls with TS during the minipuberty and the relation of the hormone serum levels with the karyotype.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive tract and breast disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON54918

Source
ToetsingOnline

Brief title
Turner minipuberty study

Condition

- Reproductive tract and breast disorders congenital
- Endocrine disorders of gonadal function
- Sexual function and fertility disorders

Synonym
Turner syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fertility, Minipuberty, Premature ovarian insufficiency, Turner Syndrome

Outcome measures

Primary outcome

Serum levels of FSH, LH, AMH, estradiol, inhibin B and testosterone.

Secondary outcome

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Study description

Background summary

Due to accelerated germ cell loss, infertility is a major problem in girls with Turner syndrom (TS). Therefore, cryopreservation of ovarian tissue or oocytes before exhaustion of the ovarian reserve may preserve fertility in patients with TS. However, in the majority of females with TS , the ovarian reserve is exhausted before the age of menarche. Early markers indicating and predicting the ovarian reserve are necessary. During mid-childhood the hypothalamic-pituitary-gonadal (HPG) axis is quiescent and gonadotropins are usually unmeasurable. Nonetheless, this axis is active during infancy. Therefore, gonadotropins are measurable with peak values at 3 months of age and with lower (but still measurable) values at 9 months of age, in a period called the minipuberty. The aim of this study is to find markers of ovarian capacity, during the minipuberty, in order to predict ovarian reserve in the future.

Study objective

The hormonal range of LH, FSH, AMH, inhibin B, testosterone and estradiol in girls with TS during the minipuberty and the relation of the hormone serum levels with the karyotype.

Study design

A prospective, cohort study with a duration of 3 years.

Study burden and risks

The subjects will have the burden of an extra venapuncture (girls with TS) or extra blood tube (controls) of 3.5 mL blood during their infancy. Venapunction is done during a regular outpatient visit to the hospital. There is very little risk for adverse events associated with this blood sample collection itself.

Adverse events that could be associated with an extra venapunction during a normal collection of blood are pain during the procedure and bruising. It could also cause psychological stress to the parents when they see the venapunction at their daughter. To minimise these adverse events, the procedure will be done by an experienced nurse and will be monitored closely. Furthermore, the burden on the parents and their daughter will be minimised by conducting the venapunction during a regular, outpatient visit within the usual care.

The information from these blood samples will be available to the parents (and later also to the girl) through their electronic patient record. A disclaimer on this information will be added to the information in the record, which will state: *The values of these hormones are taken in a study context and it is not known what they indicate about the fertility chances of your daughter. You can ask any questions about these values to your usual caregiver.* In the future, these markers might be able to support the counseling for possible fertility preservation in young girls with TS. Especially, they might become of importance in the considerations around performing cryopreservation of ovarian tissue and in the prospects regarding pubertal development.

This study can only be performed in girls with TS because they show a specific pattern of gonadal dysfunction. This study cannot be performed at a later age since the minipuberty is strictly related to the infancy period.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in the TS group of this study, a subject must meet all of the following criteria:
- A diagnosis of TS before the age of three months;
- Girls with a diagnosis of classic TS or other variants (i.e. 45,X, 45,X/46XiXq, 45,X/46,XY, 45,X/46,XX, 45,X/47,XXX, 45,X/46,X,r(X), 46,XiXq, other);
- Whose parents have agreed to participate in the study through a signed written informed consent form.

In order to be eligible to participate in the control group of this study, a subject must meet all of the following criteria:
- No diagnosis of TS or any other diagnosis that might affect the HPG axis;
- Girls that will have a blood collection within their usual care at 3 months and at 9 months of age.
- Whose parents have agreed to participate in the study through a signed informed consent form.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Any other diagnosis besides TS that might affect the HPG axis;
- Ovarian surgery in the medical history;
- Critical illness;
- The use of medication affecting the HPG axis (e.g. estrogen suppletion therapy)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-08-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-05-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04189406
CCMO	NL72128.091.20