Turner And Klinefelter Treatment Target study

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To explore the relationship between hormone levels and HRQoL in patients with TS and KS.

Ethical review	Approved WMO
Status	Pending
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON45826

Source
ToetsingOnline

Brief title
TAKTT study

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Endocrine disorders of gonadal function
- Gonadotrophin and sex hormone changes

Synonym
Klinefelter syndrome (KS), monosomy X, Turner syndroom (TS), XXY syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hormone levels, Klinefelter syndrome, Quality of life, Turner syndrome

Outcome measures

Primary outcome

To explore the relationship between thyroid hormone status* and QoL as measured by the EQ-5D-5L in patients with TS.

To explore the relationship between testosterone and QoL as measured by the EQ-5D-5L in patients with KS.

*Variable that consists of the following 6 categories:

- Overt hyperthyroidism (FT4>25pmol/L and TSH<0,4mU/L)
- Overt hypothyroidism (FT4 <11 pmol/L and TSH >4,3 mU/L)
- Subclinical hypothyroidism met TSH <10mU/L (FT4 11-25 pmol/L and TSH 4,3-10mU/L)
- Subclinical hypothyroidismmet TSH >10mU/L (FT4 11-25 pmol/L and TSH > 10mU/L)
- Subclinical hyperthyroidism (FT4 11-25 pmol/L and TSH <0,4 mU/L)
- Euthyroidism (FT4 11-25 pmol/L and TSH 0,4- 4,3 mU/L)

Secondary outcome

For TS:

The relationship between thyroid hormone status* and the CIS-20, PSS scores and hair cortisol levels.

The relationship between liver enzymes and the EQ-5D-5L, CIS-20, PSS scores and hair cortisol levels.

For KS:

The relationship between testosterone and the CIS-20, LSAS, PSS scores and hair

cortisol levels.

*Variable that consists of the following 6 categories:

- Overt hyperthyroidism (FT4>25pmol/L and TSH<0,4mU/L)

- Overt hypothyroidism (FT4 <11 pmol/L and TSH >4,3 mU/L)

- Subclinical hypothyroidism met TSH <10mU/L (FT4 11-25 pmol/L and TSH

4,3-10mU/L)

- Subclinical hypothyroidismmet TSH >10mU/L (FT4 11-25 pmol/L and TSH > 10mU/L)

- Subclinical hyperthyroidism (FT4 11-25 pmol/L and TSH <0,4 mU/L)

- Euthyroidism (FT4 11-25 pmol/L and TSH 0,4- 4,3 mU/L)

Study description

Background summary

Health Related Quality of life (HRQoL) is impaired in patients with Turner (1-5) and Klinefelter syndrome (6-8) (TS and KS). It is unknown what the optimal endocrine values are that maximize HRQoL in patients with these syndromes. Therefore we will study the relation between HRQoL and biochemical parameters in for this rare syndromes relatively large cohorts of patients with TS and KS. This information will give us essential insight that will help us improve endocrine treatment and HRQoL in these patients.

Hypothesis: Biochemical parameters are related to HRQoL in patients with TS and KS.

References:
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4. La¨aite L, La¨iene D, La¨as L. Cognition, emotions and quality of life in Lithuanian girls with Turner syndrome after growth hormone therapy discontinuation. J Pediatr Endocrinol Metab. 2010;23(5):443-50.
5. Amundson E, Boman UW, Barrenäs ML, Bryman I, Landin-Wilhelmsen K. Impact of growth hormone therapy on quality of life in adults with turner syndrome. J Clin Endocrinol Metab. 2010;95(3):1355-9.
6. Herlihy AS, McLachlan RI, Gillam L, Cock ML, Collins V, Halliday JL. The psychosocial impact of Klinefelter syndrome and factors influencing quality of life. Gen Med. 2011;13(7):632-42.
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Study objective

To explore the relationship between hormone levels and HRQoL in patients with TS and KS.

Study design

Study design:
Cross-sectional, observational, multicentre study

Methods and procedures:
To measure fatigue we will use the Checklist Individual Strength (CIS-20), for HRQoL we use the 5-level EQ-5D (EQ-5D-L5) and for stress the Perceived Stress Scale (PSS) and hair cortisol levels. For patients with KS we will also use the anxiety scale from the Liebowitz social anxiety scale (LSAS) to measure social anxiety. For patients with KS, all questions from the questionnaires will be discussed orally during a visit to the outpatients clinic. One extra tube of blood and a strand of hair will be collected during routine blood withdrawal. All other variables are already part of the standard patient care and are available in patient records. For patients with TS all information is already available and will be collected from clinical records.

Study burden and risks

For patients with KS: There are no risks associated with participation. All measurements will take place right after a planned visit at the outpatients clinic. All subjects with KS need to answer questions from four questionnaires,

which will take about 30 minutes (including collection of informed consent). The biochemical parameters we measure are already routinely assessed during the visits to the outpatients clinic. We only need to collect and store one extra tube of blood. Blood will be collected during blood withdrawal for the assessment of laboratory values needed for standard care. We will also collect one strand of hair to assess hair cortisol levels. The burden is therefore minimal.

For patients with TS: For patients with TS all information is already available and we do not need any additional measurements for these patients. Therefore there will not be any burden or risk.

There is no direct benefit for the participants, but all patients with KS and TS could benefit from better hormonal treatment in the future due to the results of this study. When the questionnaires indicate severe psychological problems, we will offer psychological care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Klinefelter or Turner syndrome as confirmed by genetic testing
- Sufficient knowledge of the Dutch language to complete the questionnaires
- At least 18 years old

Exclusion criteria

- KS: Patients not under treatment in the EMC or VUmc or no planned visits during the study period
- TS: No laboratory values or no questionnaires available in patient records
- Severe psychiatric or neurologic disorders or other reasons for inability to complete the questionnaires as assessed by the treating physician.
- Failure to obtain informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	350
Type:	Anticipated

Ethics review

Approved WMO Date:	02-10-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22530
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65814.078.18
OMON	NL-OMON22530