Turner And Klinefelter Treatment Target study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22530

Source
NTR

Brief title
TAKTT

Health condition

Turner and Klinefelter syndrome

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The relationship between thyroid hormone status and QoL as measured by the EQ-5D-5L in patients with TS. The relationship between testosterone and QoL as measured by the EQ-5D-5L in patients with KS.

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)

** aspartate aminotransferase (ASAT), alanine aminotransferase (ALAT), alkaline phosphatase (ALP), gamma-glutamyl transpeptidase (GGT), bilirubin, lactate dehydrogenase (LDH)

Study description

Background summary

Rationale: 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 treatment target values are that maximize HRQoL in patients with these syndromes. Therefore we will study the relation between HRQoL and biochemical parameters in 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. Research objectives: To explore the relationship between hormone levels and HRQoL in patients with TS and KS. Hypothesis: Biochemical parameters are related to HRQoL in patients with TS and KS. Study design: Cross-sectional, observational, multicentre study Study population: Patients with KS or TS, 18 years or older Methods and procedures: To measure fatigue we will use the Checklist Individual Strength (CIS-20), for QoL 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 including the questionnaires and laboratory values is already available and will be collected from clinical records. Main study parameters/endpoints: The relationship between different hormonal parameters and HRQoL as measured by questionnaires. The hormonal parameters we will investigate in KS are: luteinizing hormone (LH), follicle-stimulating hormone (FSH) and testosterone. For patients with Turner syndrome, we will investigate free thyroxine (FT4),

thyroid stimulating hormone (TSH) and liver enzymes, which have already been collected. The relationships between the EQ-5D-L5 score and testosterone (in patients with KS) and thyroid hormone status (in patients with TS) are the primary outcomes. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

KS: Testosterone treatment is related to QoL. TS: Thyroid hormone levels are related to QoL.

Study design

This research is cross-sectional, so at one point in time.

Intervention

None

Contacts

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Eligibility criteria

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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2019
Enrollment:	350
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-09-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45826
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8047
CCMO	NL65814.078.18
OMON	NL-OMON45826

Study results