A placebo controlled study on the effect of oxandrolone, growth hormone and low-dose estrogens on growth, psychological parameters, and characteristics of the voice in girls with Turner's syndrome.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29682

Bron
NTR

Verkorte titel
Dutch Turner-oxandrolone study

Aandoening

Girls with Turner syndrome.

Ondersteuning

Primaire sponsor: Nederlandse Groeistichting (Dutch Growth Foundation)
Overige ondersteuning: Pfizer
Eli Lilly

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The effects of the various treatment regimens will be analysed in terms of:
1. Clinical, auxological and biochemical parameters;
2. (Changes in) characteristics of the voice;
3. Psychological parameters.

Toelichting onderzoek

Achtergrond van het onderzoek

The study aims to assess the efficacy and safety of oxandrolone at a dose of either 0.06 or 0.03 mg/kg b.w./day per os versus placebo in girls with Turner syndrome who are also treated with daily subcutaneous injections of 4 IU/m2 b.s. of biosynthetic GH. Low-dose estrogens are added from the age of 12-13 years onward.

A phoniatric part of the study will investigate whether oxandrolone therapy has virilizing effects on the voice and if so, to quantify these effect.

The psychological part aims to investigate psychological effects of treatment with oxandrolone.

Doel van het onderzoek

The study aims to assess the efficacy (in terms of growth response over the years of treatment, including final height) and safety of a treatment regimen consisting of:

1. Authentic biosynthetic growth hormone (GH) in a dosage of 4 IU/m2/day between the age of 2 and 7.99 years;

2. Oxandrolone at a dose of either 0.06 or 0.03 mg/kg b.w./day per os or placebo from the age of 8 years on (when the GH-treated girls completed a full number of years of GH-treatment) until the age that final height has been achieved;

3. Low dose estrogen treatment from the age of 12 years on (when a full number of years of oxandrolon-treatment has been fulfilled) until the age that final height has been achieved.

The aim of the phoniatric part of the study is to recognize and, in case of occurrence, quantify virilizing effects on the voice during oxandrolone therapy.

The psychologic part of the study aims to investigate the psychological effects of oxandrolone treatment, especially in the fields of mood, activity level, aggression and sexuality.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

All patients will receive biosynthetic GH by means of a pen-injection system. The GH-injections will be given at a dose of 4 IU/m2 b.s./day until final heiht. The GH preparations used are Genotropin® originally manufactured by Kabi Vitrum, now Pfizer, and Humatrope®, manufactured by Eli Lilly.
From the age of 8 to 9 years the patients will be divided in three treatment regimens additional to the GH therapy:

Group A: placebo;

Group B: 0.03 mg oxandrolone/kg b.w./day per os;

Group C: 0.06 mg oxandrolone/kg b.w./day per os.

At the age of 12-13 years the girls will also receive low-dose estrogens: ethinyl estradiol 0.05 µg/kg/day per os (in the morning) or 17-ß-estradiol in an equivalent dosage.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. The diagnosis Turner syndrome should be confirmed by lymphocyte chromosomal analysis;

2. Chronological age between 2 and 15.99 years;

3. Well documented growth rate during the previous year;

4. Bone age (TW-RUS) lower than 12.0 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any endocrine or metabolic disorder, such as diabetes mellitus, diabetes insipidus or inborn errors of metabolism, with the exeption of thyroidal illnesses adequately treated/substituted;

2. Growth failure due to disorders of urinary, cardiopulmonary, gastro-intestinal and nervous system; nutritional/vitamin deficiencies and chondrodysplasias;

3. Patients with hydrocephalus;

4. Patients who have participated in other experimental drug study within 2 months of entry into the present study;

5. Patients receiving any kind of drug that may interfere with GH-therapy;

6. Previous GH, sex hormone or anabolic steroid treatment;

7. Presence of persistent abnormality at general pediatric and biochemical screening;

8. Serious suspicion of emotional deprivation or psychiatric illnesses.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-12-1991
Aantal proefpersonen:	133
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-06-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL647
NTR-old	NTR708
Ander register	: N/A
ISRCTN	Incomplete info for ISRCTN

Resultaten

Samenvatting resultaten
N/A