A placebo controlled study on the effect of oxandrolone in combination with authentic biosynthetic human growth hormone and low-dose oestrogens on growth and metabolic parameters in girls with Turner's syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23518

Source
Nationaal Trial Register

Brief title
Oxandrolone study

Health condition

girls with Turner syndrome

Sponsors and support

Primary sponsor: Pfizer (New York), previously Pharmacia; and Lilly (Indianapolis, USA)
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Final height.

Secondary outcome

Potential side effects (glucose intolerance; lowering of the voice);
psychosexual changes.

Study description

Background summary

Double-blind RCT on the effect of oxandrolone in two dosages (vs placebo) on long-term effects on growth, voice characteristics, psychosexual dedvelopment and carbohydrate metabolism.

Study objective

Adding oxandrolone to the standard treatment of GH (in adolescence combined with oestrogens) increases growth velocity and final height. Adding oxandrolone does not lead to untoward side effects, e.g. on voice characteristics.

Intervention

Three arm study:
1) GH alone (plus oestrogens in adolescence);
2) idem plus low-dose oxandrolone (0.03 mg/kg body weight/day;
3) idem plus moderate-dose oxandrolone (0.06 mg/kg/day.

Contacts

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Eligibility criteria

Inclusion criteria

Turner syndrome, confirmed by chromosomal analysis. 3 age ranges: 2.00-7.99 yrs, 8-11.99 yrs, 12.00-15.99 yrs.

Exclusion criteria

1. Any other disorder that may affect growth;

2. Hydrocephalus;
3. Other experimental drug study;

4. Drugs that may interfere with GH;

5. Previous treatment with GH or sex steroidsor anabolic steroids;

6. Suspicion of emotional deprivation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1992
Enrollment:	135
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

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
NTR-new	NL327
NTR-old	NTR365
Other	: N/A
ISRCTN	ISRCTN54336338

Study results

Summary results

N/A