

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

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/01/2012	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - Nederlandse Groeistichting

Contact details
Westzeedijk 106
Rotterdam
Netherlands
3016 AH

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

Oxandrolone study

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised double blind placebo controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Turner syndrome

Interventions

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)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oxandrolone

Primary outcome(s)

Final height.

Key secondary outcome(s)

1. Potential side effects (glucose intolerance; lowering of the voice)
2. Psychosexual changes

Completion date

01/01/2012

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

16 years

Sex

Female

Key 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 steroids or anabolic steroids
6. Suspicion of emotional deprivation

Date of first enrolment

01/01/1992

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

Netherlands

Study participating centre

Westzeedijk 106
Rotterdam
Netherlands
3016 AH

Sponsor information

Organisation

Dutch Growth Foundation (Netherlands)

Funder(s)

Funder type

Industry

Funder Name

Pfizer (Netherlands)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Lilly (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No