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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2005	**Overall study status** Completed	
Last Edited 10/01/2012	**Condition category** Other	

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

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

Primary study design
Interventional

Study design
Multicentre randomised double blind placebo controlled parallel group trial

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