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Prospective UK collaborative study of growth promoting treatment in Turner syndrome

Submission date 02/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/07/2010	**Overall study status** Completed	
Last Edited 30/06/2011	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sponsor reference number: 99/CH/02

Study information

Scientific Title
Prospective UK collaborative study of growth promoting treatment in Turner syndrome; impact of a consistent dose of growth hormone therapy and benefit of combination treatment with oxandrolone, and early or late oestrogen induction in a group of girls with Turner syndrome

Acronym
UK Turner Study

Study objectives
In a group of girls with Turner syndrome receiving a standard dose of growth hormone therapy, what is the impact on final height of:
1. Adjunctive treatment with the anabolic steroid, oxandrolone, from 9 years of age and
2. The introduction of oestrogen therapy for pubertal induction at 12 versus 14 years of age?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee (formerly Multi-Centre Research Ethics Committee for Scotland) approved on the 25th of February 1999 (ref: 98/0/092)

Study design
Multicentre randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Contact Emma-Jane Gault [EJ.Gault@clinmed.gla.ac.uk] (study research associate) for patient information (recruitment closed)

Health condition(s) or problem(s) studied
Turner syndrome, which can be defined as the loss or abnormality of the second X chromosome in a phenotypic female

Interventions
Girls with Turner syndrome receiving a standard dose of growth hormone therapy are randomised to receive oxandrolone (0.05mg/kg/day; max. dose 2.5mg/day) or placebo from 9 years until final height. Participants are further randomised at 12 years of age to either begin pubertal induction (Ethinylestradiol Yr 1: 2mcg daily/Yr 2: 4mcg daily/Yr 3: 4 months each of 6, 8, 10 mcg daily) or to receive placebo for 2 years and begin pubertal induction (as above) at 14

years of age.
Participants are followed up until final height is attained.

Joint sponsor details:
University of Glasgow
Contact:
Paul G Ellis
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University of Glasgow
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G12 8QQ

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Final adult height (cm), defined as height velocity <1 cm/year and bone age ≤15.5 years.

Secondary outcome measures
1. Maximum height, i.e. the most recently available height
2. Age of attaining final height
3. Three summary growth parameters (size, tempo, velocity)

Overall study start date
24/11/1999

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Girls with Turner syndrome, confirmed by karyotype
2. Age 7 - 13 years
3. Naive to growth hormone therapy or previous treatment within specified range (8.3-11.7mg /m2/week in 5-7 injections per week)
4. Naive to oxandrolone or oestrogen therapy
5. Open epiphyses
6. Free from major systemic illness likely to impact growth

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
13 Years

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Age 0 - 6 years or 14+ years
2. Fused epiphyses
3. Chronic illness likely to impact growth
4. Social or psychological difficulties thought likely to result in serious impairment of concordance

Date of first enrolment
24/11/1999

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow Department of Child Health
Glasgow
United Kingdom
G3 8SJ

Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

Sponsor details

Research and Development Central Office
NHS Greater Glasgow and Clyde
Western Infirmary
38 Church Street
Glasgow
United Kingdom
G11 6NT

Sponsor type
Government

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
1999 to 2004: Scottish Executive Chief Scientist Office (UK) (Ref. K/MRS/50/C2713)

Funder Name
2004 to present: British Society for Paediatric Endocrinology and Diabetes (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/04/2011		Yes	No