

Prospective UK collaborative study of growth promoting treatment in Turner syndrome

Submission date 02/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/06/2011	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 Malcolm DC Donaldson

Contact details
University of Glasgow Department of Child Health
Royal Hospital for Sick Children
Yorkhill
Glasgow
United Kingdom
G3 8SJ

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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

Senior Contracts Manager

Research & Enterprise

University of Glasgow

10 The Square

Glasgow

G12 8QQ

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

13 years

Sex

Female

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

United Kingdom

Scotland

Study participating centre

University of Glasgow Department of Child Health

Glasgow

United Kingdom

G3 8SJ

Sponsor information

Organisation

NHS Greater Glasgow & Clyde (UK)

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

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