

A randomised dose comparison study of recombinant human growth hormone effects on metabolism markers in children with growth hormone (GH) deficiency

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/10/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr NP Wright

Contact details

Division of Child Health
Sheffield Children's Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH
+44 (0)114 222 2000

Additional identifiers

Protocol serial number

N0220117222

Study information

Scientific Title

Study objectives

Is the response to growth hormone dose dependent and what are the best markers to evaluate the response?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised dose comparison study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Growth hormone deficiency

Interventions

Patients will attend a screening visit (combined with the usual visit to teach child and parent how to inject GH and familiarise them with the pen) for collection of informed consent (patients and parent/guardian). Demographic data, medical history, auxology, pubertal development and concomitant medication details will have been collected in outpatients. All these data are routinely collected as part of the normal clinical process.

Randomisation to one of three dose regimes will then take place. At entry to the study biological samples will be collected - 10 to 12 ml of blood and 24 h urine collection. These will currently be an additional investigation. Further assessment of auxological data and pubertal staging will take place after 3 months. Repeat biological samples (10 to 12 ml of blood and 24 h urine collection) will be collected. Venesection routinely takes place after 3 months treatment for clinical reasons to facilitate monitoring of insulin-like growth factor (IGF-1).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Recombinant human growth hormone

Primary outcome(s)

Measurements: Blood samples will be sent to central laboratories for analysis. Parameters to be analysed are as follows: Glucose, HbA1C, insulin, total cholesterol, triglycerides, high density

lipoproteins (HDL) and low density lipoprotein (LDL) cholesterol; bone-specific isoenzymes: calcaemia, phosphoraemia, alkaline phosphatase; markers of bone formation and resorption: osteocalcin, N-telopeptide, C-telopeptide, total deoxypyridinoline and type 3 procollagen; insulin-like growth factor 1 (IGF-1), insulin-like growth factor binding protein 3 (IGF-BP3), ALS, IGF-BP1; dehydroepiandrosterone sulphate (DHEA-S), testosterone, antimullerian hormone (AMH) (boys only); free thyroxine (FT4), leptin; parathyroid hormone (PTH) and vitamin D (25OH-D).

Evaluation of primary efficacy endpoint: This is an investigational study with a principal objective of identifying primary endpoints from a battery of biological markers for later use in a second study. Consequently this study does not have any pre-specified primary outcome measures.

Key secondary outcome(s)

Evaluation of secondary efficacy endpoints: For each of the biological markers, an appropriate parametric or non-parametric statistical analysis will be employed to investigate differences between dose groups at the 3-month assessment while adjusting for appropriate co-variates.

Completion date

30/09/2003

Eligibility

Key inclusion criteria

Recruitment and number of subjects: Maximum recruitment of five pre-pubertal newly diagnosed GH-deficient patients in whom a clinical decision is made that they would benefit from treatment with GH and who wish to take part in study (subject to inclusion/exclusion criteria in accordance with protocol).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/2002

Date of final enrolment

30/09/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Division of Child Health

Sheffield

United Kingdom

S10 2TH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Industry

Funder Name

Sheffield Childrens Hospital NHS Trust (UK)

Funder Name

Serono

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration