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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 15/10/2014	**Condition category** Nutritional, Metabolic, Endocrine	

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
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

Study design
Randomised dose comparison study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2002

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

Age group
Child

Sex
Both

Target number of participants
5

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
England

United Kingdom

Study participating centre
Division of Child Health
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Industry

Funder Name
Sheffield Childrens Hospital NHS Trust (UK)

Funder Name
Serono

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