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Pharmacokinetic studies of recombinant human insulin-like growth factor-I (rhIGF-I) in children with Crohns disease induced growth retardation

Submission date 23/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/04/2010	**Overall study status** Completed	
Last Edited 22/07/2013	**Condition category** Digestive System	

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
2007-004269-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4293

Study information

Scientific Title

Acronym
IGF in Paed Crohns

Study objectives
Growth failure occurs in approximately one third of children with Crohn's disease. Insulin-like growth factor-I (IGF-I) concentrations are depressed in active Crohn's disease, and increase to normal on entering remission with enteral feeding. Growth Hormone concentrations are normal in active disease. The children therefore exhibit a resistance to growth hormones effects.

A proportion of children do not enter remission despite state-of-the-art medications, and some of them continue to fail to grow. Treatment for the growth deficiency caused by low IGF-I activity would offer great benefits in such children.

The treatment for endocrine causes of growth hormone resistance (usually due to growth hormone receptor defects) is subcutaneous IGF-I. Furthermore, injections of human IGF have been shown, in work published from our laboratory, to enhance growth in rats with colitis. An IGF-I preparation is now available to treat children with growth hormone receptor defects, but not other conditions. A detailed understanding of the pharmacokinetics of IGF-I is needed before IGF-I can be considered as a treatment for growth faltering in children with Crohns disease. We hypothesized that subcutaneous IGF-I will increase IGF-I concentrations of children with Crohn's disease associated with low IGF-I, without serious adverse effects. To examine this hypothesis we proposed to study three specific aims:
1. To examine the effect of IGF-I on IGF-I and glucose concentrations in the circulation over 24 hours after administration in children with Crohn's disease
2. To examine the effect of daily IGF-I on IGF-I over the course of 1 week
3. To examine the pharmacokinetics of IGF-I in children with documented protein losing enteropathy

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved on the 19th December 2007 (ref: 07/h0705/77)

Study design
Non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
Increlex subcutaneously; Study Entry : Registration only

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Recombinant human insulin-like growth factor-I

Primary outcome measure
IGF-I levels

Secondary outcome measures
Blood glucose and hormones of the IGF-I axis

Overall study start date
25/09/2008

Completion date
01/07/2010

Eligibility

Key inclusion criteria
Criteria for aims 1 and 2:
1. Aged greater than 10 years, either sex
2. Height velocity measured over greater than 6 months: less than -2 SDS
3. Erythrocyte sedimentation rate: greater than 25 mm/hr
4. C-reactive protein: greater than 10 mg/l
5. Albumin greater than 40 g/l
6. Stool alpha-1-antitrypsin concentration: less than 2.0 g/l

Criteria for aim 3:
1. Aged greater than 10 years, either sex
2. Height velocity measured over greater than 6 months: less than -2 SDS
3. Erythrocyte sedimentation rate: greater than 25 mm/hr
4. C-reactive protein: greater than 10 mg/l

5. Albumin less than 35 g/l
6. Stool alpha-1-antitrypsin concentration: greater than 2.3 g/l
7. No corticosteroids for 3 months

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Sex
Both

Target number of participants
Planned Sample Size: 10; UK Sample Size: 10

Key exclusion criteria
1. Neoplasia
2. Fused epiphyses
3. Corticosteroids within last 3 months

Date of first enrolment
25/09/2008

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cell and Molecular Science
London
United Kingdom
E1 2AD

Sponsor information

Organisation
Queen Mary's School of Medicine and Dentistry (UK)

Sponsor details
Turner Street
London
England
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Sponsor type
University/education

Website
http://www.smd.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Crohn's and Colitis Foundation of America (CCFA) (USA)

Alternative Name(s)
Crohn's & Colitis Foundation of America, CCFA

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

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	28/05/2013		Yes	No