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

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