

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

<b>Submission date</b> 23/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/07/2013	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2007-004269-16

### Protocol serial number

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)

### Primary study design

Interventional

### Study design

Non-randomised interventional treatment trial

### Study type(s)

Treatment

### 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(s)**

IGF-I levels

**Key secondary outcome(s)**

Blood glucose and hormones of the IGF-I axis

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

10 Years

**Sex**

All

**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**

United Kingdom

England

**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)

**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

**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?
<a href="#">Results article</a>	results	28/05/2013		Yes	No