

# A multi-centre randomised trial of insulin detemir in pre-diabetes associated with cystic fibrosis

**Submission date**

19/09/2006

**Recruitment status**

No longer recruiting

**Registration date**

27/06/2007

**Overall study status**

Completed

**Last Edited**

15/03/2016

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ Record updated in last year

**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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Sheffield

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S10 2TH

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SCH-05-015

# Study information

## Scientific Title

A multi-centre randomised trial of insulin detemir in pre-diabetes associated with cystic fibrosis

## Study objectives

To establish a better methodology for identifying patients with Cystic Fibrosis Related Diabetes mellitus (CFRD) and to show that early treatment produces clinical benefits.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

West Midlands Research Ethics Committee, 17/10/2005

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Cystic Fibrosis Related Diabetes mellitus (CFRD)

## Interventions

Children will be randomised to receive Insulin detemir 0.2 units per kg body weight by once daily subcutaneous injection daily for one year. The control group will receive no intervention. There is no placebo or sham treatment (it was not felt appropriate given that it would require a daily injection).

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Insulin detemir

**Primary outcome measure**

Measurements of beta-cell function

**Secondary outcome measures**

1. Height, weight, Body Mass Index (BMI), triceps and biceps skin fold thickness
2. Respiratory function testing
3. Three monthly glycosylated haemoglobin
4. Adverse event monitoring

**Overall study start date**

01/10/2006

**Completion date**

01/11/2009

**Eligibility****Key inclusion criteria**

Any child over ten years of age with either fasting plasma glucose more than 6.1 mmol/l but less than 7.0 mmol/l and/or a two hour glucose of more than 7.8 mmol/l but less than 11.1 mmol/l.

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

10 Years

**Sex**

Both

**Target number of participants**

240

**Key exclusion criteria**

1. Failure to provide informed consent
2. Pre-existing insulin or oral hypoglycaemic agent treatment

**Date of first enrolment**

01/10/2006

**Date of final enrolment**

01/11/2009

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Sheffield Children's NHS Foundation Trust**  
Sheffield  
United Kingdom  
S10 2TH

## **Sponsor information**

**Organisation**  
Sheffield Children's NHS Foundation Trust (UK)

**Sponsor details**  
Clinical Research Support Unit  
D41 Stephenson Wing  
Western Bank  
Sheffield  
England  
United Kingdom  
S10 2TH  
+44 (0)114 2260507  
vee.mapunde@sch.nhs.uk

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.sheffieldchildrens.nhs.uk/>

**ROR**  
<https://ror.org/02md8hv62>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**

British Society of Paediatric Endocrinology and Diabetes (UK) - Initial funding of £10,000 in November 2004

**Funder Name**

Sheffield Children's Appeal Charity (UK) - £32,000 in early 2005

**Funder Name**

Novo Nordisk (UK) - the makers of Detemir; £72,000 (post MREC approval) in summer 2005

## **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