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

Submission date	Recruitment status	[ ] Prospectively registered
19/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/06/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2016	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
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 subcutanous 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