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

Summary

EudraCT number	2005-002997-31
Trial protocol	GB
Global end of trial date	11 January 2010

Results information

Result version number	v1 (current)
This version publication date	21 December 2019
First version publication date	21 December 2019
Summary attachment (see zip file)	end of trial letter to MHRA (end of study MHRA reply.pdf) end of declaration form (end of trial declaration form.pdf)

Trial information

Trial identification

Sponsor protocol code	SCH/05/015

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sheffield Children's Hospital NHS Foundation Trust
Sponsor organisation address	Western Bank, Sheffield, United Kingdom, S10 2TH
Public contact	Dominic Nash, Sheffield Children's Hospital NHS Foundation Trust, 44 01143053478, dominic.nash@nhs.net
Scientific contact	Dominic Nash, Sheffield Children's Hospital NHS Foundation Trust, 44 01143053478, dominic.nash@nhs.net

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	11 January 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 January 2010
Global end of trial reached?	Yes
Global end of trial date	11 January 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To examine whether treatment with a long acting insulin analogue in the prediabetic phase improves growth & lung function and whether it delays progression to the development of overt diabetes in cystic fibrosis

Protection of trial subjects:
None
Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	17 October 2005
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	40
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study duration will be 3 years – 2 years for recruitment and 1 year for run-out. The expected total duration of participation in the study for each participant is 12 months. The end of trial is 12 months after the recruitment of the last patient.

Pre-assignment

Screening details:

Not applicable

Period 1

Period 1 title	overall trial
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Arm title	intervention

Arm description:

insulin detemir 0.2u/kg given as a single daily dose before breakfast

Arm type	Experimental
Investigational medicinal product name	insulin determir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular and intravenous use

Dosage and administration details:

insulin detemir 0.2u/kg given as a single daily dose before breakfast

Number of subjects in period 1	intervention
Started	40
Completed	40

Period 2

Period 2 title	control
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details: Not applicable

Arms

Arm title	control
Arm description: No injection given	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	control
Started	40
Completed	40

Baseline characteristics

End points

End points reporting groups

Reporting group title	intervention
Reporting group description:	
insulin detemir 0.2u/kg given as a single daily dose before breakfast	
Reporting group title	control
Reporting group description:	
No injection given	

Primary: end of study

End point title	end of study[1]

End point description:

1. Measurements of beta-cell function. Multiple regression models will be constructed to examine which measures of beta cell function and glucose tolerance at baseline best predict future glucose tolerance, pulmonary function and clinical status at 12 months.
2. height, weight, BMI, triceps and biceps skin fold thickness
3. respiratory function testing including measurement of FEV1, FVC, Shwachman score and record of respiratory exacerbations
4. 3 monthly glycosylated haemoglobin, examination of home testing blood sugar profiles
5. Adverse event monitoring (complications of CF, hypoglycaemia, other side effects).

End point type	Primary

End point timeframe:

end of study

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Previous studies of insulin in CFRD shoed a difference in FVC of 12.6% (SD+/- 5.0%) and in FEV1 of 6.5% (SD +/- 4.0) following treatment. Assuming a much smaller 5% difference in FVC & FEV1 only 15 children are needed in each arm of the treatment aspect of the study to demonstrate a significant beneficial effect of insulin (95% confidence – 80% power) No other statistical analysis was performed

End point values	intervention	control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: NA	40	40		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Duration of trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No serious adverse events were reported

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 October 2007	Dr Fiona Campbell is to replace Dr Steven Conway as principal investigator at the Leeds site

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported