ISRCTN77773974 https://doi.org/10.1186/ISRCTN77773974

A randomised study of continuous subcutaneous insulin infusion (CSII) therapy compared to conventional bolus insulin treatment in preschool aged children with Type 1 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/11/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Carlo Acerini

Contact details
Department of Paediatrics
Box No 116
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 336865
cla22@cam.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544116582

Study information

Scientific Title

Study objectives
To establish whether treatment with CSII therapy results in better blood glucose control, reduced hypoglycaemia frequency, preserved endogenous insulin secretion and in improved quality of life measures in parents and families of preschool aged children with diabetes, compared to those treated with conventional bolus subcutaneous insulin injection (CIT) regimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Randomised Controlled trial:
A. Continuous subcutaneous insulin infusion (CSII)
B. Conventional bolus insulin treatment

This study aims to establish whether continuous subcutaneous insulin infusion (CSII) therapy has advantages over conventional bolus insulin injection treatment (CIT) in children less than 5 years

of age with Type 1 (insulin dependent) diabetes mellitus, particularly in terms of improved blood glucose control, reduced hypoglycaemia frequency and improved parental quality of life (QoL) measures. A randomised controlled study will be carried out, with newly diagnosed children with diabetes (aged <5 years) assigned to treatment with either CSII (n = 10) or CIT (n= 10). All participating children and their families will be regularly reviewed in the diabetes clinic setting and will have support from the paediatric diabetes team as per normal clinical routine. At 3 to 6 month intervals 24 h blood glucose profiles will be performed using a subcutaneous continuous glucose monitoring sensor (CGMS) device and parental QoL questionnaires will be completed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
12/09/2002

Completion date
11/09/2005

Reason abandoned (if study stopped)
1. Lack of funding/sponsorship 2. Participant recruitment issue

Eligibility

Key inclusion criteria
20 children <5 years with type 1 diabetes

Participant type(s)
Patient

Age group
Child

Upper age limit
5 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
12/09/2002

Date of final enrolment
11/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Paediatrics
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name
Cambridge Consortium - Addenbrookes (UK) (NHS R&D Support Funding + Addenbrooke's Charitable Funds)

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