

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/11/2009	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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## 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