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# SCIPI - Subcutaneous Insulin: Pumps or Injections

| Submission date | Recruitment status |
|---|---|
| 10/11/2010 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 12/11/2010 | Completed |
| **Last Edited** | **Condition category** |
| 16/08/2018 | Nutritional, Metabolic, Endocrine |

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Type 1 diabetes is a lifelong condition that occurs when the pancreas doesn't produce any insulin, the hormone that controls the amount of glucose (sugar) in the blood. This causes a person's blood glucose level to become too high. About 24,000 children and young people living in the UK have type 1 diabetes. Treatment requires adherence to a daily routine of multiple insulin injections and blood glucose tests. The effect of unplanned food, exercise, stress and illness on blood glucose levels also has to be anticipated and accommodated in the daily treatment plan. This routine and the symptoms of uncontrolled high or low blood glucose levels can adversely impact the quality of life of affected children and young people. In the longer term complications such as kidney failure, diseases of the heart and nervous system, sight loss and amputations also affect quality of life and reduce life expectancy by 20 years. Good blood glucose control and intensive insulin treatments minimise the risk of developing these complications. Blood glucose control is assessed from a blood test that measures glycosylated haemoglobin (HbA1c). There are two forms of intensive treatment: administration of insulin by multiple daily injections or using a pump. Pump therapy is 6 times more expensive than multiple daily injections. If HbA1c or quality of life is better during pump therapy this may be a good investment for the NHS. However, if pump therapy is no better than multiple daily injections, investment in diabetes care may be better directed elsewhere. This study aims to compare the outcomes of patients treated with multiple daily injections to those using pumps one and five years after diagnosis of type 1 diabetes.

Who can participate?
Children and young people (age 6 months to 15 years) with type 1 diabetes

What does the study involve?
Participants are randomly allocated to receive insulin either by multiple daily injections or pumps. All patients are educated to match insulin dose to carbohydrate intake, exercise and blood glucose readings. Patients receiving pumps are educated in their use. Patients are telephoned daily for 1 week, weekly for 1 month and monthly thereafter. Patients also have access to telephone advice. All contacts are logged. The following measurements are made at the start of the study and every 3 months for 1 year: HbA1c, body mass index, height, insulin dose and adverse events (uncontrolled high or low blood glucose levels). Quality of life is

assessed at the start of the study and after 6 and 12 months using questionnaires. HbA1c is compared between the two groups at 1 year.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Alder Hey Children's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2011 to June 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Joanne Blair
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Joanne Blair

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# Additional identifiers

### Clinical Trials Information System (CTIS)
2010-023792-25

### Protocol serial number
HTA 08/14/39

# Study information

### Scientific Title

A randomised controlled trial of continuous subcutaneous insulin infusion (CSII) compared to multiple daily injection (MDI) regimens in children and young people at diagnosis of type I diabetes mellitus (TIDM)

## Acronym
SCIPI

## Study objectives
This study is designed to provide an evidence base to inform future NHS investment in health care services for children and young people with TIDM. The role of intensive insulin therapy in optimizing glycaemic control and thereby reducing the risk of vascular complications of TIDM is unquestioned, however the optimal way in which to achieve this and the cost effectiveness of the tools currently available is unknown. This study will compare two methods of insulin delivery during childhood and adolescence to identify which facilitates superior glycaemic control, and examine the impact of treatment modalities on other predictors of vascular complications of TIDM, adverse events and quality of life (QoL).

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/081439
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0005/52385/PRO-08-14-39.pdf

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Pending at time of registration

## Study design
Open labelled two-arm randomised controlled trial with an inbuilt pilot

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Children with Type 1 Diabetes Mellitus

## Interventions
Participants will be randomised in a 1:1 ratio to either of the two treatments
1. Arm A (Multiple Dose Injection of Insulin (MDI) treatment): Insulin aspart and insulin glargine will be delivered subcutaneously using an insulin pen injection device
2. Arm B (Continuous Subcutaneous Insulin Infusion (CSII) treatment): Insulin aspart will be administered using CSII insulin pumps
The total duration for both the treatment arms is 1 year including and participants will be followed for the duration of the intervention.

## Intervention Type
Mixed

### Primary outcome(s)
Pilot study
Fifty percent or more subjects who are eligible and are invited to participate in the pilot study are successfully recruited.

Full study
Glycaemic control (HbA1c) 12 months after diagnosis

### Key secondary outcome(s))
Pilot study
Demographic characteristics like age, gender and deprivation score are not significantly different in the group of subjects who are recruited compared to those who decline. These characteristics will be measured at the end of the pilot phase (at 6 months) before open the trial for full study.

Full study
1. Percentage of patients in each group with HbA1c <7.5%, measured at baseline, 3, 6, 9 and 12 months
2. Prevalence of adverse events (including severe hypoglycaemia) at 3, 6, 9 and 12 months
3. Change in Body Mass Index Standard Deviation Score (BMI SDS) at 3, 6, 9 and 12 months
4. Insulin requirements (units / kg /day) at 3, 6, 9 and 12 months
5. Quality of Life (QoL) assessed by PedsQL questionnaire at baseline, 6 and 12 months
6. Incremental cost per Quality-Adjusted Life-Year (QALY) gained at 12 months

### Completion date
30/06/2014

## Eligibility

### Key inclusion criteria
1. Newly diagnosed TIDM using standard diagnostic practise (WHO Definition 2006)
2. Age 6 months - 15 years (inclusive)
3. Willing to give consent for the study

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
6 months

### Upper age limit
15 years

### Sex

All

### Key exclusion criteria
1. Treated previously for diabetes
2. Haemoglobinopathy
3. Co-existing pathology conditions likely to affect glycaemic control, e.g. cystic fibrosis
4. Psychological or psychiatric disorders, e.g. eating disorder
5. Receipt of medication likely to affect glycaemic control, e.g. systemic or high dose topical corticosteroid or growth hormone therapy
6. Allergy to a component of insulin aspart or insulin glargine
7. Patient who have a first degree relative with existing TIDM

Patients previously diagnosed with coeliac disease or thyroid dysfunction will be eligible to join the study if they have maintained a gluten-free diet/been maintained in a euthyroid state for 3 months prior to the diagnosis of TIDM.

### Date of first enrolment
03/01/2011

### Date of final enrolment
30/06/2014

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Alder Hey Children's NHS Foundation Trust**
Liverpool
United Kingdom
L12 2AP

## Sponsor information

### Organisation
Alder Hey Children's NHS Foundation Trust (UK)

### ROR
https://ror.org/00p18zw56

## Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/08/2018 | | Yes | No |
| Protocol article | protocol | 16/04/2015 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |