

SCIP - Subcutaneous Insulin: Pumps or Injections

Submission date 10/11/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/08/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

EudraCT/CTIS number
2010-023792-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 1 diabetes mellitus (T1DM)

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 T1DM. The role of intensive insulin therapy in optimizing glycaemic control and thereby reducing the risk of vascular complications of T1DM 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 T1DM, 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not yet available in web format, please use contact details below to request a patient information sheet .

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 measure

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

Secondary outcome measures

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

Overall study start date

03/01/2011

Completion date

30/06/2014

Eligibility

Key inclusion criteria

1. Newly diagnosed T1DM 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

Age group

Child

Lower age limit

6 Months

Upper age limit

15 Years

Sex

Both

Target number of participants

316

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 T1DM

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 T1DM.

Date of first enrolment

03/01/2011

Date of final enrolment

30/06/2014

Locations

Countries of recruitment

England

United Kingdom

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)

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00p18zw56>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

01/02/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

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