

Comparison in metabolic control and treatment satisfaction with continuous subcutaneous insulin infusion and multiple daily injections in children at onset of type 1 diabetes mellitus

Submission date
29/04/2007

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
03/07/2007

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
16/05/2019

Condition category
Nutritional, Metabolic, Endocrine

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

N/A

Study information

Scientific Title

Comparison in metabolic control and treatment satisfaction with continuous subcutaneous insulin infusion and multiple daily injections in children at onset of type 1 diabetes mellitus

Study objectives

To compare treatment satisfaction with Continuous Subcutaneous Insulin Infusion (CSII) and Multiple Daily Injections (MDI) in newly diagnosed diabetic children and adolescents. Our outcome measurements are metabolic control, safety and treatment satisfaction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Uppsala University (Sweden), approved on 11th October 2001 (ref: Ups dnr 01-347)

Study design

Open, randomized, parallel group study.

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Type 1 diabetes mellitus

Interventions

Group 1: Continuous subcutaneous insulin infusion for 24 months

Group 2: Multiple daily insulin injections for 24 months

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

insulin

Primary outcome(s)

The following were measured at baseline, 1 month, 6, 12 and 24 months:

1. Metabolic control (HbA1c)

2. Treatment satisfaction (Questionnaires Diabetes Treatment Satisfaction Questionnaire [DTSQ])
3. Safety (Registration of hospitalization for ketoacidosis [defined as pH <7.3] and major hypoglycemic episodes and/or technical problems)

Key secondary outcome(s)

The following were measured at baseline, 1 month, 6, 12 and 24 months:

1. BMI
2. Insulin requirement
3. Adverse events
4. C-peptide
5. insulin-like growth factor-1 (IGF-1)
6. Binding proteins

Completion date

31/05/2006

Eligibility

Key inclusion criteria

Children and adolescents (age 7 to 17 years) with newly diagnosed (within 3 weeks) type 1 diabetes mellitus.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

17 years

Sex

Not Specified

Total final enrolment

72

Key exclusion criteria

Other relevant diseases.

Date of first enrolment

01/12/2001

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

Sweden

Study participating centre

Pediatric Clinic

Gävle

Sweden

S-80187

Sponsor information

Organisation

County of Gävleborg (Sweden)

Funder(s)

Funder type

Government

Funder Name

Research and Development Center, County of Gävleborg (Sweden)

Funder Name

Foundation for Children with Diabetes (Barndiabetesfonden) (Sweden)

Results and Publications

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?
Results article	results	01/10/2008	16/05/2019	Yes	No