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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

Registration date
03/07/2007

Overall study status
Completed

Last Edited
16/05/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lars Skogsberg

Contact details
Pediatric Clinic
Gävle Hospital
Gävle
Sweden
S-80187
-
lars.skogsberg@lg.se

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 (Qestionnaires 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. Isulin requirment
3. Adverse events
4. C-petide
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 relavent 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