

# 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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**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Not Specified

**Participant information sheet**

**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 measure**

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)

**Secondary outcome measures**

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

**Overall study start date**

01/12/2001

**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

**Age group**

Child

**Lower age limit**

7 Years

**Upper age limit**

17 Years

**Sex**

Not Specified

**Target number of participants**

72 patients

**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)

**Sponsor details**

Gävle Hospital

Gävle

Sweden

S-80187

**Sponsor type**

Government

**Website**

<http://www.lg.se>

## **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

**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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2008	16/05/2019	Yes	No