

# Comparison between continuous subcutaneous insulin infusion with multiple basal lispro infusion rates and multiple daily insulin injection with lispro and glargine

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|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>18/04/2007   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>25/04/2007 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>22/09/2021       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input checked="" type="checkbox"/> Results          |
|                                        |                                                                | <input type="checkbox"/> 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

### Protocol serial number

N/A

## Study information

**Scientific Title**

Comparison between continuous subcutaneous insulin infusion with multiple basal lispro infusion rates and multiple daily insulin injection with lispro and glargine

**Study objectives**

Blood glucose variability is lower during Continuous Subcutaneous Insulin Infusion (CSII) as compared to Multiple Daily Insulin injection (MDI) with Glargine.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the local ethics committee (Regione del Veneto, Azienda Ospedaliera di Padova, Comitato Etico per la Sperimentazione) on the 10th February 2003 (ref: 12998).

**Study design**

Multicentre, randomised, cross-over study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Diabetes mellitus type one

**Interventions**

Patients were randomly assigned to Continuous Subcutaneous Insulin Infusion (CSII) with lispro or Multiple Daily Injections (MDI) with lispro and glargine. After four months they were switched to the alternative treatment.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Lispro, glargine

**Primary outcome(s)**

Blood glucose variability as measure by standard deviation of mean blood glucose.

Data of the last month of each treatment period were analysed.

**Key secondary outcome(s))**

1. HbA1c
2. Quality of metabolic control characterised by the mean Blood Glucose (BG) during the last month of the respective treatment period

3. Mean and the standard deviation of the weekly BG (altogether and at the different points in time)
4. Frequency of BG greater than 8.0 mmol/l
5. Frequency of BG less than 3.5 mmol/l with or without any symptoms of hypoglycaemia
6. Frequency of severe hypoglycaemia (BG less than 2.0 mmol/l)
7. Frequency of severe hypoglycaemia (BG less than 2.0 mmol/l) day over
8. Frequency of severe hypoglycaemia (BG less than 2.0 mmol/l) night over
9. Frequency of Diabetic Ketoacidosis (DKA)
10. Frequency of hospitalisation or the use of an ambulance due to hypoglycaemic or ketotic /ketoacidotic events
11. Number of daily BG measurements
12. Daily insulin requirement (basal/preprandial, meal and correction boluses)
13. Number of daily glargine injections
14. Body weight
15. Treatment satisfaction measured by Diabetes Treatment Satisfaction Questionnaire (DTSQ)

Data of the last month of each treatment period were analysed.

**Completion date**

16/05/2005

## Eligibility

**Key inclusion criteria**

1. Type one diabetic patients (World Health Organisation [WHO] classification)
2. Between 18 and 60 years old
3. Have been diabetics for more than two years
4. Have been treated with CSII for at least six months prior to the study
5. HbA1c needs to be less than 8.5%
6. Patients should be familiar with carbohydrate counting and should be able to change insulin doses (either by pump or injections) based on changes in food intake and physical exercise

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

60 years

**Sex**

Not Specified

**Key exclusion criteria**

1. Poor motivation
2. Body Mass Index (BMI) greater than 30 kg/m<sup>2</sup>
3. Treatment with daily insulin injections
4. Inability to handle pump therapy (pump handling, infusion set handling, compliance with treatment rules)
5. Untreated retinopathy

**Date of first enrolment**

24/07/2003

**Date of final enrolment**

16/05/2005

**Locations****Countries of recruitment**

Italy

**Study participating centre**

Azienda Ospedaliera di Padova

Padova

Italy

35128

**Sponsor information****Organisation**

Disetronic Medical Systems AG (Switzerland)

**ROR**

<https://ror.org/00by1q217>

**Funder(s)****Funder type**

Industry

**Funder Name**

Disetronic Medical Systems AG (Switzerland)

# 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 27/02/2008   | 22/09/2021 | Yes            | No              |