

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

Submission date 18/04/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/04/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/09/2021	Condition category 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
Dr Daniela Bruttomesso

Contact details
Azienda Ospedaliera di Padova
Dipartimento di Medicina Clinica e Sperimentale
Cattedra Malattie del Metabolismo
2, Via Nicolò Giustiniani
Padova
Italy
35128

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

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

Secondary outcome measures

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.

Overall study start date

24/07/2003

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Not Specified

Target number of participants

50

Key exclusion criteria

1. Poor motivation
2. Body Mass Index (BMI) greater than 30 kg/m²
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)

Sponsor details

Kirchbergstrasse 190
Burgdorf
Switzerland
3401

Sponsor type

Industry

Website

<http://www.disetronic.com>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Disetronic Medical Systems AG (Switzerland)

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?
Results article		27/02/2008	22/09/2021	Yes	No