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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

Registration date
25/04/2007

Overall study status
Completed

Last Edited
22/09/2021

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

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Additional identifiers

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).

Primary study design
Interventional

Study design
Multicentre, randomised, cross-over study

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 metablic 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^2
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?
Results article		27/02/2008	22/09/2021	Yes	No