ISRCTN68954085 https://doi.org/10.1186/ISRCTN68954085

Reduction of severe hypoglycaemia with continuous intraperitoneal insulin infusion in type one diabetic patients unsuccessfully treated by continuous subcutaneous insulin infusion

Submission date
17/09/2006

Registration date
15/11/2006

Last Edited
08/09/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andreas Liebl

Contact details
Woernerweg 30
Bad Heilbrunn
Germany
83670
dr.liebl@t-online.de

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
DiaPort Study

Study objectives
Objective:
Continuous intraperitoneal insulin infusion (CIPII) with the DiaPort system using regular insulin was compared to continuous subcutaneous insulin infusion (CSII) using insulin Lispro, to investigate the frequency of hypoglycaemias, blood glucose control, quality of life, and safety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethical Committee of the Bayerische Landesärztekammer in Munich, September 2000.

Study design
Open, randomised, controlled, cross-over, multinational, 12-month study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus type one

Interventions
60 type one diabetic patients with frequent hypoglycaemias and/or HbA1c greater than 7.0% with CSII were randomised to CIPII or CSII. The aim was to obtain the best possible blood glucose while avoiding hypoglycaemias.

1. Patients in the CSII group continued their CSII using insulin Lispro
2. Patients in the CIPII group had an implantation of a percutaneous DiaPort system under general anesthesia. The catheter was placed into the peritoneal cavity. The exact localisation of the DiaPort was chosen individually according to the regular habits and clothing of the patients. Mostly the port was implanted into the lower right or left quadrant of the abdomen. CSII was terminated, and the insulin pump was connected to the DiaPort. The insulin dosage was optimised during the stay in hospital and at each visit.

In both treatment groups, the target was to obtain fasting and pre-prandial blood glucose values between 80 - 120 mg/dl, and average blood glucose values below 150 mg/dl, while avoiding hypoglycemias at the same time. Also, in both groups H-TRONplus insulin pumps from Roche Diagnostics were used. For intraperitoneal infusion only regular insulin for pumps (Insuman Infusat® or H-tronin®, Aventis®) was administered.

In both groups, there were regular evaluations of diabetes complications, vital parameters, HbA1c, safety laboratory data (one central laboratory for all study sites), abdominal ultrasound examination, quality of life (using the Diabetes Quality of Life measure [DQoL]), port-related complications, and photographic documentation.

The patients performed and documented at least four blood glucose self measurements daily (prior to each main meal and just before bedtime). Before visits, additional measurements (two hours after each meal and during night time between 2:00 and 3:00 am) were performed.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Insulin Infusion

Primary outcome(s)
The primary endpoint of the study was the frequency of hypoglycaemias (defined as blood glucose below 54 mg/dl [3 mmol/l]) per patient year with CIPII using DiaPort in comparison to CSII with insulin Lispro.

Key secondary outcome(s))
1. Frequency of severe hypoglycaemias (defined by hospitalisation, unconsciousness, seizures or intravenous glucose administration)
2. Metabolic control (HbA1c, blood glucose, blood glucose fluctuations)
3. Quality of life (DQoL)
4. Safety of CIPII with DiaPort in comparison to CSII

Completion date
31/12/2001

Eligibility

Key inclusion criteria
1. Male or female patients at least 18 years of age
2. Type one diabetes
3. Unsuccessfully treated with CSII (i.e. frequent hypoglycaemias according to the assessment of the investigator and/or HbA1c above 7.0%)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Lack of cooperation or of mental capacity
2. Pregnancy or wish for pregnancy
3. Abuse of alcohol or drugs
4. Lack of personal hygiene
5. Frequent change of treating physicians
6. Severe liver disease
7. Current malignant disease
8. Human immunodeficiency virus (HIV) infection
9. Continuous ambulatory peritoneal dialysis
10. Contraindications for anaesthesia or surgical operations
11. Severe eating disorders
12. Severe psychological or psychiatric disorders
13. Lack of willingness to perform at least four blood glucose self-measurements per day

Date of first enrolment
01/10/2000

Date of final enrolment
31/12/2001

Locations

Countries of recruitment
Austria

France

Germany

Netherlands

Switzerland

Study participating centre
Woernerweg 30
Bad Heilbrunn
Germany
83670

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