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# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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.

### Secondary outcome measures
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

### Overall study start date
01/10/2000

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### Target number of participants
62

### 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**
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# Sponsor information

**Organisation**
Disetronic Medical Systems AG (Switzerland)

**Sponsor details**
Kirchbergstrasse 190
Burgdorf
Switzerland
CH-3401

**Sponsor type**
Industry

**Website**
http://www.disetronic.com/disetronic.asp?menuId=2&languageId=2

**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