Comparison of insulin absorption after administration of insulin lispro with a patch-pump versus a catheter based pump and the effect of catheter wear-time

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To measure serum insulin and glucose profiles after bolus insulin administration by a patch-pump versus a catheter based pump, reproducibility of these insulin profiles and the effect of catheter wear-time on these profiles in patients with type 1...

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON36179

Source
ToetsingOnline

Brief title
CIPHER Trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Subsidie Europese Unie

Intervention

Keyword: CSII, diabetes, insulin

Outcome measures

Primary outcome

The primary endpoint will be time to peak serum insulin levels following administration of the mealtime insulin bolus with CP and PP, and coefficient of variation (CV) of basal and postprandial insulin levels after CP and PP.

Secondary outcome

Secondary endpoints will include postprandial glucose excursions, early insulin t50% and area under the curve for insulin levels, Maximum concentration of insulin levels, delta baseline to peak in insulin levels and coefficient of variation of basal insulin levels. Of the secondary endpoints listed above the same will be determined for glucose levels after administration of mealtime bolus.

Study description

Background summary

Most closed loop approaches rely on subcutaneous administration of insulin by means of conventional insulin pumps (i.e. pumps with a catheter). Until recently all insulin pumps consisted of a needle inserted into the subcutaneous tissue, a pump (containing the insulin, electronic, pump and batteries) and a catheter connecting these two parts. Recently patch-pumps were developed, to be carried directly on the skin, without the need to insert a needle manually and without a visible catheter. Internally these patch-pump still employ a catheter

of about 50 mm; however, substantially less than the 600 mm of catheter tubing used with catheter based pumps. For Artificial Pancreas (AP) development it is highly relevant to know if patch-pumps and conventional pumps have different insulin absorption rates and reproducibility of insulin absorption. Recent evidence suggests that the duration of the insulin catheter usage (wear-time) also influences the speed of insulin absorption from the subcutaneous tissue, as the time to maximal insulin levels seems to move forward in time with a longer wear-time.

Study objective

To measure serum insulin and glucose profiles after bolus insulin administration by a patch-pump versus a catheter based pump, reproducibility of these insulin profiles and the effect of catheter wear-time on these profiles in patients with type 1 diabetes.

Study design

The study will be a randomised open-label trial with a cross-over design.

Intervention

The study will consist of the measurement of glucose and serum insulin levels at baseline and following a meal. Patients with Type 1 diabetes will come in for two blocks of visits: one block of two visits (48 h apart) while wearing the Omnipod Insulin Pump (PP) and one block of two visits while wearing a Medtronic Paradigm Pump (CP). The visit blocks will be in random order, using a crossover design. For study visits, patients will report to the clinical research unit in a fasting state in the early morning hours and blood sampling for insulin levels will start to record baseline values. Patients will then be served an individually standardized breakfast and mealtime insulin bolus (at least 6 U).
The two visits in a given block will be 48 hours apart. We will use the second visits in each block to perform a separate analysis investigating the effect of catheter wear-time.

Study burden and risks

Patients will visit the clinical research center (CRC) for an inclusion visit; this visit will take approximately 1 hour to complete. When eligible to participate in the study; patients will visit the CRC 4 times. Two times wearing the PP and two times wearing the CP. Estimated duration of these visits is 5.5 hours per visit, totalling 23 hours of time spent in the CRC for the duration of the entire study. Blood samples will be drawn during the CRC admissions. Risk to the patient includes haematoma or infection around the blood collection catheter sites or the insulin catheter / insulin pod insertion

site. This risk is known to be very low with currently available insulin pump devices. A maximum volume of 310 mL of blood will be drawn during the entire duration of the study.

Contacts

Public
Academisch Medisch Centrum

Postbus 22660
1100DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Postbus 22660
1100DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Aged 18 years or above
Diagnosed with Type 1 DM at least 6 months according to the WHO definition
Treated with CSII or MDII for at least 3 months
Body Mass Index (BMI) <35 kg/m²
HbA1c measured during the last three months between 6 and 10%
Using <66 insulin units per day on average.

Exclusion criteria

Patient is pregnant or breastfeeding
Patient is using a medication which significantly impacts glucose metabolism, except if stable for at least 3 months
Patient has a severe medical or psychological condition which, in the opinion of the investigator, prohibits participation in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2011
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	Insulin pumps (Medtronic Paradigm series and the Omnipod)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35409.018.11