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Optimal time of mealtime insulin administration in people with type 1 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
15/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/03/2010	Nutritional, Metabolic, Endocrine	[ ] 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
Optimal Lag Time Study: Optimal timing of rapid-acting insulin analogues administration before meals

Acronym
OLTS

Study objectives
We hypothesize that mealtime insulin administration at 30 or 15 minutes before the start of a meal will result in reduced postprandial glycemic excursions when compared to insulin administration simultaneously with the start of a meal.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee of Academic Medical Centre, Amsterdam approved on the 22nd of January 2009 (ref: MEC 08/349 # 09.17.0121)

Study design
Single-centre randomised open label controlled crossover intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 1 diabetes and postprandial glycemic conditions.

Interventions
Ten type 1 diabetics who had been on CSII for at least six months were included in the study. On the day before the first test meal, patients received a subcutaneous CGM sensor (Medtronic CGMS SofSensor) during a visit to the outpatient clinic and were instructed to calibrate the sensor at home according to the manufacturers specifications.
The next day at 08:00 am, patients reported on an empty stomach to the clinical research unit and were admitted. Patients received an intravenous catheter for blood collection. Before the

start of the daily study protocol blood glucose was measured by finger prick. If blood glucose was between 3.0 mmol/L and 7.8 mmol/L, the study protocol would commence immediately. If the blood glucose was too high, intravenous insulin aspart was administered. If blood glucose had been corrected to acceptable parameters and if these values remained stable (excursions < 0.6mmol/L) over a period of 1 hour, the study protocol commenced.
Patients were randomized on each study day by means of opaque, sealed envelopes which were sequentially numbered, between insulin bolus administration at three strata; -30, -15 or 0 minutes before the meal. Each patient was provided with a meal that was comparable to their regular morning meal, the meal for one individual patient did not differ over study days. The first hour before the meal blood was sampled every 15 minutes, the first 2 hours after the meal every 10 minutes and the third and fourth hour after the meal every 20 minutes. Blood samples were collected in 2cc sodium fluoride tubes for determination of blood glucose. The insulin bolus was administered by the patients according to their own calculation of carbohydrates in the meal (at this point estimated to be between 4 and 12 IU per meal, depending on the patient and their respective meals).
After the test meal and blood collection, patients would go home continuing to wear the CGM sensor and reported back to the clinical research unit the next day to continue the protocol until all three insulin administration strata had been completed.

After the three study-meals, there is no additional follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
All outcomes in this study are outcomes derived from the postprandial glucose curve, and as such are a measure of postprandial glucose control on the three study days until 5 hours postprandially.

Secondary outcome measures
1. Continuous Glucose Monitoring (CGM) values
2. Number and duration of hypoglycemias
3. Maximum swing of blood-glucose levels
4. Highest blood glucose levels
5. Lowest blood glucose levels
6. Time spent in hyperglycemia

Overall study start date
01/10/2009

Completion date
30/03/2010

Eligibility

Key inclusion criteria
1. Men or women aged from 18 to 75 years
2. Type 1 diabetes according to the WHO definition

3. Treated with insulin for at least 2 years and by Continuous Subcutaneous Insulin Infusion (CSII) for at least 6 months
4. Body mass index (BMI) < 35 kg/m2
5. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
10

Key exclusion criteria
1. Pregnancy (women of childbearing potential must have an adequate contraception) or breastfeeding
2. Treatment with systemic corticosteroids
3. Treatment with oral antidiabetics within 1 week prior to the first study day
4. Impaired renal function as shown by serum creatinine ≥ 133 umol/l in men or ≥ 124 umol/l in women
5. Known impaired hepatic function defined as alanine aminotransferase (ALAT) and / or aspartamine aminotransferase (ASAT) three times greater the upper limit of the normal range
6. Alcohol or drug abuse in the last year
7. Mental condition rendering the patient unable to understand the nature and scope of the study

Date of first enrolment
01/10/2009

Date of final enrolment
30/03/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
POBox 22660
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

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