

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

<b>Submission date</b> 15/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/03/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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.

### **Key secondary outcome(s)**

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

### **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/m<sup>2</sup>
5. Written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

Not Specified

**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  $\geq 133$   $\mu\text{mol/l}$  in men or  $\geq 124$   $\mu\text{mol/l}$  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)

**ROR**

<https://ror.org/03t4gr691>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Academic Medical Centre (AMC) (Netherlands)

## 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes