

# The necessity of an injection-meal-interval in patients with type 2 diabetes mellitus and therapy with human insulin

**Submission date**

14/08/2007

**Recruitment status**

No longer recruiting

**Registration date**

12/09/2007

**Overall study status**

Completed

**Last Edited**

01/02/2019

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00529165

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Randomized crossover study to examine the necessity of an injection-to-meal interval in patients with type 2 diabetes and human insulin

## Study objectives

There is no difference in metabolic control in patients with type 2 diabetes mellitus and therapy with human insulin with or without injection-meal-interval.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Friedrich Schiller University Ethics Committee on the 10th October 2006 (ref: 1855-09/06).

## Study design

Monocentric, open, randomised, two-phased, cross-over design.

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Diabetes mellitus type 2

## Interventions

The patient injects human insulin (as Actrapid from NovoNordisc) as usual in their insulin routine. The injection is subcutaneous and the dosage is dependent on the blood glucose monitoring. Patients will inject insulin previous every meal, with the following differences:

1. Group A: with injection-meal-interval: 50 patients educated to inject the insulin with an injection-meal-interval of 15 minutes
2. Group B: without injection-meal-interval: 50 patients educated to inject the insulin without injection-meal-interval

Cross-over will occur to the other group after 12 weeks. The follow up is 28 weeks.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Human insulin

**Primary outcome measure**

HbA1c, measured from venous blood samples from the finger at baseline and weeks 4, 16 and 28.

**Secondary outcome measures**

1. Frequency of hypoglycaemia, measured at 4 and 28 weeks
2. Quality of life, measured using the Audit of Diabetes-Dependent Quality of Life (ADDQoL) at weeks 4, 16 and 28
3. Satisfaction of quality of care, measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) at weeks 4, 16 and 28

**Overall study start date**

01/07/2007

**Completion date**

01/07/2008

**Eligibility****Key inclusion criteria**

1. Type 2 diabetes mellitus
2. Aged 40 - 80 years
3. Therapy with human insulin

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Pregnancy
2. Nutrition disorders
3. Psychological disease
4. Body Mass Index (BMI) less than 25 kg/m<sup>2</sup>
5. HbA1c greater than 9%

**Date of first enrolment**

01/07/2007

**Date of final enrolment**

01/07/2008

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

University Hospital Jena

Jena

Germany

07743

## **Sponsor information**

**Organisation**

University Hospital Jena (Germany)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uniklinikum-jena.de/Willkommen.html>

**ROR**

<https://ror.org/035rzx15>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

University of Jena (Germany)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2013	01/02/2019	Yes	No