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

Submission date	Recruitment status	[_] Prospectively registered
14/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2019	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00529165

Protocol serial number
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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnancy
2. Nutrition disorders
3. Psychological disease
4. Body Mass Index (BMI) less than 25 kg/m^2
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
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07743

Sponsor information

Organisation
University Hospital Jena (Germany)

ROR
https://ror.org/035rzkx15

Funder(s)

Funder type
University/education

Funder Name
University of Jena (Germany)

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?
Results article	results	01/07/2013	01/02/2019	Yes	No