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Differences in glucose production, lipolysis and proteolysis during different BASal INsulins, in patients with type two diabetes

Submission date	Recruitment status	[X] Prospectively registered
30/05/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/05/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/10/2021	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

Protocol serial number
NL926 (NTR950)

Study information

Scientific Title

Differences in glucose production, lipolysis and proteolysis during different BASal INsulins, in patients with type two diabetes

Acronym
BASIN

Study objectives
Differences exist in duration of effect of insulin detemir, insulin glargine or Neutral Protamine Hagedorn (NPH) insulin on glucose production, lipolysis and proteolysis in patients with type two diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group, multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes Mellitus type 2 (DM type II)

Interventions
The patients are admitted to the metabolic unit of the Academic Medical Centre at 4.30 pm, with the last meal and usual insulin dosage of short-acting insulin taken at 12.00 am. The long-acting insulin is injected in the subcutis of the thigh at bedtime. Measurements of Hepatic Glucose Production (HGP), lipolysis and proteolysis will start one hour after the administration of the basal insulin at bedtime.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
1. Hepatic Glucose Production (HGP)
2. Lipolysis
3. Proteolysis

Key secondary outcome(s))

1. Plasma Glucose
2. Free fatty acids levels

Completion date
01/08/2008

Eligibility

Key inclusion criteria
1. Caucasian male patients with Diabetes Mellitus Type Two (DM II)
2. Basal bolus insulin therapy with NPH, detemir or glargine for at least one year
3. Basal insulin dosage: 30 ± 10 U
4. Fasting plasma glucose: 7.5 - 10.0 mmol/l
5. HbA1c 7.5 - 9%
6. Age 40 to 65 years
7. Body Mass Index (BMI) 26 - 30 kg/m^2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Major flaws in injection technique, as indicated by subcutaneous infiltration
2. Creatinine greater than 100 µmol/L or diabetic nephropathy
3. Abnormal liver enzymes (greater than 2 x upper limit of normal) and fasting triglycerides greater than 3 mmol/L
4. Clinically manifest autonomic neuropathy
5. Macrovascular complications of DM II, except for peripheral arterial disease
6. Epilepsy
7. Drugs interfering with insulin sensitivity and lipolysis, other than metformin
8. Alcohol abuse (greater than 5/day)
9. Fever/infection
10. Dietary fat content greater than 75%

Date of first enrolment
01/08/2007

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Novo Nordisk (Denmark)

Alternative Name(s)
Novo Nordisk Global

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration