

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

Submission date 30/05/2007	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 30/05/2007	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/10/2021	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ 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

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group, multicentre trial

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/m²

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