

A comparison of once daily insulin detemir given pre-breakfast or bedtime, according to need, with bedtime insulin glargine in people with type 2 diabetes characterised by an asymmetric insulin requirement across the day and night

Submission date 08/03/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 08/03/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/08/2009	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR585

Study information

Scientific Title

Added 24/08/09: A multicentre, open-label, randomized comparison of once daily insulin detemir given pre-breakfast or bedtime, according to need, with bedtime insulin glargine in people with type 2 diabetes characterized by an asymmetric insulin requirement between the day and night.

Acronym

BIRDSONG-trial

Study objectives

Insulin detemir, when injected once daily at an individually appropriate time (either before breakfast or at bedtime), provides superior glycaemic control to insulin glargine injected indiscriminately at bedtime in patients that had clearly different dose requirements, day and night, when their insulin was previously given as a twice daily regimen.

Basal Insulin Requirement for Diabetes with Sunrise Or Nightfall Glucose escape (BIRDSONG)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised open label active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes mellitus type II (DM type II)

Interventions

Randomisation will be to once-daily insulin glargine given at bedtime (or late evening) or to insulin detemir given once daily either at this time or before breakfast, according to the patient subgroup. The initial insulin dose will be determined as the greater of the two prior daily insulin doses. OGLD therapy will remain unchanged throughout the trial.

Each treatment period will be for 16 weeks, involving forced dose titration throughout. Insulin dose will be continually titrated against pre-breakfast or pre-dinner (depending on group) plasma glucose, and will be curtailed by confirmed hypoglycaemia at any time. For those receiving insulin detemir pre-breakfast, the titration target is pre-dinner plasma glucose <5.6 mmol/l. For those receiving insulin glargine or insulin detemir at bedtime the target is pre-breakfast plasma glucose <5.6 mmol/l.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The percentage of participants achieving the following criteria: pre-breakfast plasma glucose <5.6 mmol/l and pre-dinner plasma glucose <6.9 mmol/l, without hypoglycaemia, confirmed by a blood glucose reading of <3.5 mmol/l.

Secondary outcome measures

1. HbA1c at endpoint
- 2 Change in HbA1c over the study
3. Mean and coefficient of variation of fasting and pre-dinner blood glucose levels
4. 9-point blood glucose profiles
5. Hypoglycaemia event rates throughout the study period and in last 12 weeks of study
6. Body weight at baseline and at endpoint
7. Blood pressure
8. Triglycerides, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol
9. Skin reactions to insulin injection, as reported by patients

Overall study start date

01/04/2006

Completion date

30/11/2006

Eligibility

Key inclusion criteria

People with type 2 diabetes who have received treatment with either twice daily NPH insulin or a twice daily regimen of a human or analogue (30/70) premix insulin, either regimen for at least 2 months, with or without concomitant use of oral glucose-lowering drugs (OGLDs) and:

1. A ratio of evening insulin dose:morning insulin dose >1.3:1 (nocturnal hepatic glucose output

subgroup), or

2. A ratio of morning insulin dose:evening insulin dose >1.3:1 (daytime insulin insensitivity subgroup)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

175

Key exclusion criteria

1. Patients with HbA1c >9.0 or <6.5% at entry visit
2. Patients with body mass index >40.0 kg/m² at entry visit
3. Patients who are pregnant or for whom pregnancy during the trial is a possibility
4. Patients currently receiving treatment with thiazolidinediones or meglitinide derivatives, that cannot be stopped for the duration of the trial
5. Patients with high insulin dose requirements >100 U/day at entry visit
6. Patients on mixed insulin regimens, such as NPH insulin and a premixed insulin, or different ratios of premixed insulin morning and evening
7. Patients with known or suspected allergy to trial products or related products
8. Any condition that the local investigator feels would interfere with trial participation or the evaluation of results

Date of first enrolment

01/04/2006

Date of final enrolment

30/11/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

Sponsor details

P.O. Box 22660
Amsterdam
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Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)**Funder type**

Industry

Funder Name

Novo Nordisk BV (Netherlands)

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