ISRCTN06622595 https://doi.org/10.1186/ISRCTN06622595

# 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

**Registration date**
08/03/2006

**Overall study status**
Completed

**Last Edited**
24/08/2009

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr S.G.H.A. Swinnen

**Contact details**
Academic Medical Center
Department of Internal Medicine F4-257
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5667836
S.G.Swinnen@amc.uva.nl

## Additional identifiers

**Protocol serial number**

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

### Study type(s)
Treatment

### 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(s)
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.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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)

### ROR
https://ror.org/03t4gr691

## Funder(s)

### Funder type
Industry

**Funder Name**
Novo Nordisk BV (Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration