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 characterized by an asymmetric insulin requirement across the day and night.

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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...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25809

Bron
Nationaal Trial Register

Verkorte titel
BIRDSONG-trial - Basal Insulin Requirement for Diabetes with Sunrise Or Nightfall Glucose escape.

Aandoening

Type 2 diabetes.

Ondersteuning

Primaire sponsor: Dr. J.H. de Vries
Academic Medical Center - Amsterdam
and

Prof. Philip Home
University of Newcastle upon Tyne, UK
Overige ondersteuning: Novo Nordisk Farma BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Study title:

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 characterized by an asymmetric insulin requirement across the day and night.

Background:

As type 2 diabetes progresses, insulin therapy is generally needed to maintain acceptable blood glucose control. Traditionally, insulin therapy was often initiated by the addition, to prior oral glucose-lowering drugs (OGLDs), of twice daily injections of insulin formulations with an extended duration of action, such as NPH insulin. In recent years, the availability of the long-acting basal insulin analogues insulin glargine and detemir has led to the increasing introduction of insulin therapy by once-daily injection.

Yet, it is not unusual for people with type 2 diabetes to have different supplementary insulin requirements during the daytime and night-time. Accordingly, a formulation like insulin glargine, with a relatively flat profile of action reaching out to 24 hours, may imperfectly match the insulin supplementation needs of either group, whenever given. This suggests that an insulin with intermediate properties, such as insulin detemir, might, if injected at times aimed at matching the patient’s physiological requirement, provide optimal control of hyperglycaemia, without causing the hypoglycaemia that can limit dose titration in clinical practice.

Objective:

The primary objective of this study is to assess whether insulin detemir, when injected once-daily at an individually appropriate time (either before breakfast or at bedtime), can provide 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.

Design and methods:

The trial is an open-label, randomized, twin parallel-group clinical trial in people with type 2 diabetes characterized by an asymmetrical insulin requirement across the day and night.

Population:

People with type 2 diabetes who have received treatment with either twice daily NPH insulin or a twice daily regimen of a premix insulin, for at least 2 months, with or without concomitant use of 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).

Intervention:

Randomization will be to once-daily insulin glargine given at bedtime or to insulin detemir given once daily either at this time or before breakfast, according to the patient subgroup. 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.

Primary endpoint:

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.

Burden for the participants:

The risk for participants is judged to be minor. During treatment with insulin analogues there haven’t occurred any other side-effects than those during other insulin therapy. The main side-effect of any type of insulin therapy is the risk of hypoglycaemia. Participation mainly requires an investment of time.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Randomization 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.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 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 OGLDs, and;

2. A ratio of evening insulin dose:morning insulin dose >1.3:1 (nocturnal hepatic glucose output subgroup), or

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-04-2006
Aantal proefpersonen:	175
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-02-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL541
NTR-old	NTR585
Ander register	: N/A
ISRCTN	ISRCTN06622595

Resultaten

Samenvatting resultaten
N/A