

Observational Study on Levemir® in Obese Diabetic Patients (KILOS)

This study is currently recruiting participants.

Verified by Novo Nordisk, February 2009

First Received: February 20, 2009 No Changes Posted

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00849342

▶ Purpose

This study is conducted in Europe. The aim of this observational study is to investigate the effect of switch from other basal insulin treatments to Levemir® on body weight in obese diabetic patients.

<u>Condition</u>	<u>Intervention</u>
Diabetes Mellitus	Drug: insulin detemir

[MedlinePlus](#) related topics: [Diabetes](#) [Obesity](#) [Obesity in Children](#)

[Drug Information](#) available for: [Insulin](#) [Insulin Detemir](#)

[U.S. FDA Resources](#)

Study Type: Observational

Study Design: Case-Only, Prospective

Official Title: A Prospective, Multicentre, Non-Controlled, Observational, 52-Weeks Study: the Evaluation of the Body Weight Progress During the Treatment With Insulin Detemir in **Type 1** or **2 Diabetes** Patients, Previously Treated With Other Basal Insulins.

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- Change in body weight and BMI [Time Frame: during 12 months of treatment] [Designated as safety issue: No]

Secondary Outcome Measures:

- Change in body weight at different BMI subgroups [Time Frame: at insulin start, 12 and 6 months before treatment and after 3, 6, 9 and 12 months of treatment] [Designated as safety issue: No]
- Change in waist perimeter [Time Frame: from insulin start and after 6 and 12 months of treatment] [Designated as safety issue: No]
- Change in FPG (Fasting Plasma Glucose) [Time Frame: from 12 and 6 months before treatment after 6 and 12 months of treatment] [Designated as safety issue: No]
- Change in HbA1C [Time Frame: from insulin start and 12 and 6 months before treatment and after 6 and 12 months of treatment] [Designated as safety issue: No]
- Change in number of hypoglycaemic events during 4 weeks proceeding routine visits [Time Frame: after 6 and 12 months of treatment] [Designated as safety issue: No]
- Number of adverse drug reactions (ADR) [Time Frame: after 6 and 12 months of treatment] [Designated as safety issue: Yes]
- Change in blood pressure [Time Frame: from insulin start and 6 and 12 months after treatment] [Designated as safety issue: No]

Biospecimen Retention: None Retained

Biospecimen Description:

Estimated Enrollment: 200

Study Start Date: January 2009

Estimated Study Completion Date: November 2010

Estimated Primary Completion Date: November 2010 (Final data collection date for primary outcome measure)

<u>Groups/Cohorts</u>	<u>Assigned Interventions</u>
A	Drug: insulin detemir Safety and effectiveness(weight and HbA1c) data collection in connection with the use of the drug Levemir® in daily clinical practice.

▶ Eligibility

Ages Eligible for Study:	6 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Patients from both general and speciality practice settings who have been deemed appropriate to receive Levemir® because of weight increase on other insulin therapies, and as part of routine out-patient care by the prescribing physician.

Criteria

Inclusion Criteria:

- Diabetes mellitus (Type 1 or type 2)
- BMI greater than 27 kg/m², or more than 3 kg weight increase since start of insulin therapy

Exclusion Criteria:

- Subjects currently being treated with insulin detemir
- Subjects who were previously enrolled in this study;
- Subjects with a hypersensitivity to insulin detemir or to any of the excipients.
- Women who are pregnant, breast feeding or have the intention of becoming pregnant within next 12 months Female patients will be reminded to use adequate contraceptive during the study, where is relevant.

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00849342

Contacts

Contact: Public Access to Clinical Trials - Novo Nordisk	Please Contact NN via email	clinicaltrials@novonordisk.com
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Locations

Netherlands

Recruiting

Alphen a/d Rijn, Netherlands

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Sarita Kesarlal, MSc Novo Nordisk B.V.

Study Director: Piet van der Wal, MD, PhD Novo Nordisk B.V.

▶ **More Information**

Additional Information:

[Clinical Trials at Novo Nordisk](#) EXIT

No publications provided

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)

Study ID Numbers: NN304-3708

Study First Received: February 20, 2009

Last Updated: February 20, 2009

ClinicalTrials.gov Identifier: [NCT00849342](#) [History of Changes](#)

Health Authority: Netherlands: Medicines Evaluation Board, Dutch Health Care Inspectorate

Study placed in the following topic categories:

Body Weight	Endocrine System Diseases
Obesity	Endocrinopathy
Hypoglycemic Agents	Glucose Metabolism Disorders
Metabolic Diseases	Metabolic Disorder
Diabetes Mellitus	Insulin

Additional relevant MeSH terms:

Hypoglycemic Agents	Diabetes Mellitus
Metabolic Diseases	Glucose Metabolism Disorders
Physiological Effects of Drugs	Pharmacologic Actions
Endocrine System Diseases	Insulin

ClinicalTrials.gov processed this record on April 16, 2009