

# Observational Study in Type 2 Diabetics Failing on Oral Antidiabetic Therapy and Starting on Insulin Treatment (HA-BOT)

**This study is currently recruiting participants.**

Verified by Novo Nordisk, March 2009

First Received: March 18, 2009 No Changes Posted

<b>Sponsored by:</b>	<b>Novo Nordisk</b>
<b>Information provided by:</b>	Novo Nordisk
<b>ClinicalTrials.gov Identifier:</b>	NCT00865397

## ▶ Purpose

This study is conducted in Europe. The aim of this observational study is to evaluate glycaemic control in **type 2** patients using once daily Levemir® as initiation of insulin therapy in Hungary.

<u>Condition</u>	<u>Intervention</u>
<b>Diabetes Mellitus, Type 2</b>	Drug: insulin detemir

[MedlinePlus](#) related topics: [Diabetes](#)

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

[U.S. FDA Resources](#)

Study Type: Observational

Type:

Study Design: Case Control, Prospective

Design:

Official Title: Observational Study of Glycaemic Control in **Type 2** Diabetic Patients Uncontrolled on Oral Antidiabetic Agents and Starting With Once Daily Levemir® (Insulin Detemir) - 24 Weeks, Prospective, Multicentre Observational Study in Hungary

**Further study details as provided by Novo Nordisk:**

Primary Outcome Measures:

- Change in HbA1c [ Time Frame: after 24 weeks ]  
[ Designated as safety issue: No ]

Secondary Outcome Measures:

- Percentage of subjects to reach HbA1c below 7.0% and equal to or more than 6.5% [ Time Frame: after 12 weeks and 24 weeks ]  
[ Designated as safety issue: No ]
- Change in FPG (Fasting Plasma Glucose) [ Time Frame: after 12 weeks and 24 weeks ] [ Designated as safety issue: No ]
- Change in body weight [ Time Frame: after 12 weeks and 24 weeks ]  
[ Designated as safety issue: No ]
- Change in waist and hip circumference [ Time Frame: after 12 weeks and 24 weeks ] [ Designated as safety issue: No ]

Biospecimen Retention: None Retained

Biospecimen Description:

Estimated Enrollment: 1000

Study Start Date: February 2009

Estimated Study Completion Date: February 2010

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

<u>Groups/Cohorts</u>	<u>Assigned Interventions</u>
A	Drug: insulin detemir Effectiveness data collection in connection with the use of the drug Levemir® in daily clinical practice.

 **Eligibility**

Genders Eligible for Study: Both  
Accepts Healthy Volunteers: No  
Sampling Method: Non-Probability Sample

**Study Population**

A non-randomised sample of approximately 1000 subjects with OAD failure from specialists - diabetologists practice who have been deemed appropriate to receive insulin detemir as add-on to OAD therapy as part of routine out-patient care by the prescribing physician.

## Criteria

### Inclusion Criteria:

- Patient with type 2 diabetes inadequately controlled by OAD therapy based on the discretion of individual physician
- Patient willing to sign informed consent
- Particular attention should be paid to age limits, indications and contraindications and the drug interactions that are listed within the product labels

### Exclusion Criteria:

- Subjects with diagnosed type 1 diabetes mellitus
- Subjects who are unlikely to comply with observational plan, (e.g., uncooperative attitude, inability to return for further visits)
- Subjects with hypersensitivity to Levemir® or to any of the ingredients
- Women of childbearing potential, who are pregnant, breast-feeding or intend to become pregnant within next 12 months.

## ▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00865397

## Contacts

Contact: Public Access to  
Clinical Trials - Novo Nordisk

Please Contact  
NN via email

[clinicaltrials@novonordisk.com](mailto:clinicaltrials@novonordisk.com)

## Locations

### Hungary

#### Recruiting

Budapest, Hungary, H-1025

### Sponsors and Collaborators

**Novo Nordisk**

### Investigators

Study Director: Peter Varnai, MD Novo Nordisk Hungary Ltd.

## ▶ **More Information**

Additional Information:

[Clinical Trials at Novo Nordisk](#) 

No publications provided

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

Study ID Numbers: NN304-3699

Study First Received: March 18, 2009

Last Updated: March 18, 2009

ClinicalTrials.gov Identifier: [NCT00865397](#) [History of Changes](#)

Health Authority: Hungary: National Institute of Pharmacy

Study placed in the following topic categories:

Hypoglycemic Agents

Metabolic Diseases

Diabetes Mellitus, Type 2

Diabetes Mellitus

Endocrine System Diseases

Endocrinopathy

Glucose Metabolism Disorders

Metabolic Disorder

Insulin

Additional relevant MeSH terms:

Hypoglycemic Agents

Metabolic Diseases

Physiological Effects of Drugs

Endocrine System Diseases

**Diabetes Mellitus, Type 2**

**Diabetes Mellitus**

Glucose Metabolism Disorders

Pharmacologic Actions

Insulin