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To Evaluate the Effect of Liraglutide Versus Glimepiride (Amaryl®) on Haemoglobin A1c (LEAD 3)

This study is ongoing, but not recruiting participants.

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00294723

Purpose

Double blind trial with two open label extensions conducted in the United States of America (USA) and Mexico.

Trial dates:

Original trial: Start February 2006, finish November 2007 First extension: Start March 2007, finish November 2008

Second extension: Start March 2008, finish November 2011 The trial is designed to evaluate the effects of treatment with liraglutide versus glimepiride in subjects with type 2 diabetes

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: liraglutide Drug: glimepiride	Phase III

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

[Drug Information](#) available for: [Liraglutide](#) [Glimepiride](#)

[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Double Blind (Subject, Investigator), Active Control, Parallel Assignment, Safety/Efficacy Study

Official Title: Liraglutide Effect and Action in Diabetes (LEAD 3): Effect on Glycemic Control of Liraglutide Versus Glimepiride in Type 2 Diabetes.

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- Change in HbA1c [Time Frame: after 52 weeks, after 104 weeks and after 245 weeks]
[Designated as safety issue: No]

Secondary Outcome Measures:

- Body weight [Time Frame: after 52 weeks, after 104 weeks and after 245 weeks]
[Designated as safety issue: No]
- Safety and tolerability [Time Frame: during treatment] [Designated as safety issue: Yes]
- Glycemic Control [Time Frame: after 52 weeks, after 104 weeks and after 245 weeks]
[Designated as safety issue: Yes]

Estimated Enrollment:	175
Study Start Date:	February 2006
Estimated Study Completion Date:	November 2011
Estimated Primary Completion Date:	November 2011 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
A: Experimental	Drug: liraglutide 1.2 mg for s.c. injection
B: Experimental	Drug: liraglutide 1.8 mg for s.c. injection
C: Active Comparator	Drug: glimepiride 8 mg capsule, low dose
D: Active Comparator	Drug: glimepiride 8 mg capsule, high dose

► Eligibility

Ages Eligible for Study: 18 Years to 80 Years
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Type 2 diabetes
- Treatment with diet/exercise or with oral anti-diabetic drugs alone for at least 2 months
- Diet/exercise treated subjects with HbA1c > 7.0% and < 11%
- OAD treated subjects with HbA1c > 7.0% and < 10%
- Body Mass Index (BMI) less than or equal to 45 kg/m²

Exclusion Criteria:

- Treatment with insulin for the last 3 months
- Treatment with any drug that could interfere with the glucose level (besides use of a single anti-diabetic compound)
- Any serious medical condition

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00294723

 [Show 110 Study Locations](#)

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Paula Hale, MD Novo Nordisk

► More Information

[Clinical Trials at Novo Nordisk](#) 

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

Study ID Numbers: NN2211-1573
Study First Received: February 20, 2006
Last Updated: October 20, 2008
ClinicalTrials.gov Identifier: [NCT00294723](#) [\[history\]](#)
Health Authority: Mexico: Federal Commission for Protection Against Health Risks; United States: Food and Drug Administration

Study placed in the following topic categories:

Glimepiride
Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus

Endocrine System Diseases
Endocrinopathy
Metabolic disorder
Glucose Metabolism Disorders

Additional relevant MeSH terms:

Hypoglycemic Agents
Immunologic Factors
Therapeutic Uses
Physiological Effects of Drugs

Cardiovascular Agents
Anti-Arrhythmia Agents
Immunosuppressive Agents
Pharmacologic Actions

ClinicalTrials.gov processed this record on January 16, 2009

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