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Our Notarization Process

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AFFIDAVIT OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive. I make this declaration of my own personal knowledge.
2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.
3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.
4. The archived data made viewable and browsable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.
5. The Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]` aka an "extended URL". Thus, the extended URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` would be the URL for the record of the Internet Archive home page HTML file (`http://www.archive.org/`) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.
6. Attached hereto as Exhibit A are true and accurate copies of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.





7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: 02/02/2023

Nathaniel Frank-White
Nathaniel E Frank-White

Please see attached
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for additional
Notary Events



JURAT ATTACHMENT

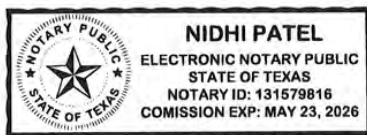
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STATE OF Texas }

COUNTY OF Harris }

The foregoing instrument was subscribed and sworn before me this date of
02/02/2023, by Nathaniel Frank-White

This notarial act was an online notarization.



(Notary Seal)

Notary's Signature 

Registration No.: 131579816

Commission Expiration Date: May 23, 2026



EXHIBIT A

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Related Studies

A Randomised Controlled Clinical Trial in Type 2 Diabetes Comparing Semaglutide to Placebo and Liraglutide

This study has been completed.

First Received on June 11, 2008. Last Updated on September 22, 2011 [History of Changes](#)

Sponsor:	Novo Nordisk
Information provided by (Responsible Party):	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00696657

Purpose

This trial was conducted in Europe, Asia and Africa. Study participants were randomised evenly to treatment with semaglutide (0.1 mg QW - 1.6 mg QW, 6 treatment arms, placebo or liraglutide (1.2 mg QD, or 1.8 mg QD). Treatment allocation to semaglutide or placebo was double-blind, whereas liraglutide treatment was administered open-label. Primary efficacy parameter was HbA1c and the treatment duration was 12 weeks.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: semaglutide Drug: placebo Drug: liraglutide	Phase II

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: Investigation of Safety and Efficacy of Five Doses of Semaglutide Versus Placebo and Open-label Liraglutide, as Add on Therapy, in Subjects Diagnosed With Type 2 Diabetes Currently Treated With Metformin or Controlled With Diet and Exercise A 12 Week Multi-centre, Multi National, Double-blind, Placebo-controlled, Randomised, Nine Armed Parallel Group, Dose Finding Trial

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [6q24-related transient neonatal diabetes mellitus](#)

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

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

[U.S. FDA Resources](#)

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]

Secondary Outcome Measures:

- Percentage of subjects with an adverse events [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]
- Percentage of subjects with hypoglycaemic episode [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]
- Change from baseline in ECG [Time Frame: week 0, week 12] [Designated as safety issue: No]
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- Change from baseline in calcitonin [Time Frame: week 0, week 12] [Designated as safety issue: No]
- Percentage of subjects developing anti-semaglutide antibodies [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]

Enrollment: 415
Study Start Date: June 2008
Study Completion Date: February 2009
Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental Intervention: Drug: semaglutide	Drug: semaglutide 0.1 mg, once weekly, s.c. injection
B: Experimental Intervention: Drug: semaglutide	Drug: semaglutide 0.2 mg, once weekly, s.c. injection
C: Experimental Intervention: Drug: semaglutide	Drug: semaglutide 0.4 mg, once weekly, s.c. injection
D: Experimental Intervention: Drug: semaglutide	Drug: semaglutide 0.8 mg, once weekly, s.c. injection

E: Experimental Intervention: Drug: semaglutide	Drug: semaglutide 0.8 mg with titration, once weekly, s.c. injection
F: Experimental Intervention: Drug: semaglutide	Drug: semaglutide 1.6 mg with titration, once weekly, s.c. injection
G1: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.1 mg, once weekly, s.c. injection
G2: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.2 mg, once weekly, s.c. injection
G3: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.4 mg, once weekly, s.c. injection
G4: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G5: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G6: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 1.6 mg, once weekly, s.c. injection
H: Experimental Intervention: Drug: liraglutide	Drug: liraglutide 1.2 mg with titration, once daily, s.c. injection
I: Experimental Intervention: Drug: liraglutide	Drug: liraglutide 1.8 mg with titration, once daily, s.c. injection

► Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Men and women-not-of-childbearing potential diagnosed with type 2 diabetes for at least three months
- Stable treatment regimen with either metformin (at least 1500 mg) or diet and exercise alone for at least three months
- HbA1c: 7.0-10.0 % (both inclusive)
- Body weight between 60 kg and 110 kg

Exclusion Criteria:

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- Impaired liver or kidney function
- Proliferative retinopathy or maculopathy requiring acute treatment
- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension
- Recurrent major hypoglycaemia or hypoglycaemic unawareness
- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00696657

Locations

Austria
Wien, Austria, 1010

Bulgaria
Russe, Bulgaria, 7000

Finland
Turku, Finland, 20520

Former Serbia and Montenegro
Belgrade, Former Serbia and Montenegro, 11000

France
MONTPELLIER cedex 5, France, 34295

Germany
Pohlheim, Germany, 35415

Hungary
Budapest, Hungary, H-1045

India
Chennai, India, 600086

Italy
Chieti Scalo, Italy, 66013

South Africa
Durban, KwaZulu-Natal, South Africa, 4091

Spain
Almería, Spain, 04001

Switzerland
Genève 14, Switzerland, 1211

Turkey
Istanbul, Turkey, 34390

United Kingdom

Bexhill-on-Sea, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk

► **More Information**

Additional Information:

[Clinical Trials at Novo Nordisk](#) external link

No publications provided

Responsible Party: Novo Nordisk
ClinicalTrials.gov Identifier: [NCT00696657](#) [History of Changes](#)
Other Study ID Numbers: NN9535-1821, 2007-003956-12
Study First Received: June 11, 2008
Last Updated: September 22, 2011
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: Finnish Medicines Agency; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Additional relevant MeSH terms:

Diabetes Mellitus
Diabetes Mellitus, Type 2
Glucose Metabolism Disorders
Metabolic Diseases
Endocrine System Diseases
Glucagon-Like Peptide 1

Incretins
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Pharmacologic Actions

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A Randomised Controlled Clinical Trial in Type 2 Diabetes Comparing Semaglutide to Placebo and Liraglutide

This study has been completed.

First Received on June 11, 2008. Last Updated on March 16, 2011 [History of Changes](#)

Sponsor:	Novo Nordisk
Information provided by:	Novo Nordisk
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Purpose

This trial was conducted in Europe, Asia and Africa. Study participants were randomised evenly to treatment with semaglutide (0.1 mg QW - 1.6 mg QW, 6 treatment arms, placebo or liraglutide (1.2 mg QD, or 1.8 mg QD). Treatment allocation to semaglutide or placebo was double-blind, whereas liraglutide treatment was administered open-label. Primary efficacy parameter was HbA1c and the treatment duration was 12 weeks.

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Resource links provided by NLM:

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

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

[U.S. FDA Resources](#)

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]

Secondary Outcome Measures:

- Percentage of subjects with an adverse events [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]
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G5: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G6: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 1.6 mg, once weekly, s.c. injection
H: Experimental Intervention: Drug: liraglutide	Drug: liraglutide 1.2 mg with titration, once daily, s.c. injection
I: Experimental Intervention: Drug: liraglutide	Drug: liraglutide 1.8 mg with titration, once daily, s.c. injection

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Ages Eligible for Study: 18 Years and older
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Criteria

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Please refer to this study by its ClinicalTrials.gov Identifier: NCT00696657

Locations

Austria
Wien, Austria, 1010

Bulgaria
Russe, Bulgaria, 7000

Finland
Oulu, Finland, 90029

Former Serbia and Montenegro
Belgrade, Former Serbia and Montenegro, 11000

France
MONTPELLIER cedex 5, France, 34295

Germany
Pohlheim, Germany, 35415

Hungary
Budapest, Hungary, H-1045

India
Chennai, India, 600020

Italy
Chieti Scalo, Italy, 66013

South Africa
Cape Town, Western Cape, South Africa, 7925

Spain
Almería, Spain, 04001

Switzerland
Küssnacht, Switzerland, 8700

Turkey
Istanbul, Turkey, 34390

United Kingdom

Bexhill-on-Sea, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk

► **More Information**

Additional Information:

[Clinical Trials at Novo Nordisk](#) external link

No publications provided

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
ClinicalTrials.gov Identifier: [NCT00696657](#) [History of Changes](#)
Other Study ID Numbers: NN9535-1821, 2007-003956-12
Study First Received: June 11, 2008
Last Updated: March 16, 2011
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: Finnish Medicines Agency; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Additional relevant MeSH terms:

Diabetes Mellitus
Diabetes Mellitus, Type 2
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Endocrine System Diseases
Glucagon-Like Peptide 1

Incretins
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Pharmacologic Actions

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

[U.S. FDA Resources](#)

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]

Secondary Outcome Measures:

- Percentage of subjects with an adverse events [Time Frame: after 12 weeks of treatment] [Designated as safety issue: No]
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- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension
- Recurrent major hypoglycaemia or hypoglycaemic unawareness
- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov Identifier: NCT00696657

Locations

Austria
Wien, Austria, 1010

Bulgaria
Russe, Bulgaria, 7000

Finland
Oulu, Finland, 90029

Former Serbia and Montenegro
Belgrade, Former Serbia and Montenegro, 11000

France
MONTPELLIER cedex 5, France, 34295

Germany
Pohlheim, Germany, 35415

Hungary
Budapest, Hungary, H-1045

India
Chennai, India, 600020

Italy
Chieti Scalo, Italy, 66013

South Africa
Cape Town, Western Cape, South Africa, 7925

Spain
Almeria, Spain, 04001

Switzerland
Küsnacht, Switzerland, 8700

Turkey
Istanbul, Turkey, 34390

United Kingdom
Bexhill-on-Sea, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk

► **More Information**

Additional Information:

[Clinical Trials at Novo Nordisk](#) external link

No publications provided

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
ClinicalTrials.gov Identifier: [NCT00696657](#) [History of Changes](#)
Other Study ID Numbers: NN9535-1821, 2007-003956-12
Study First Received: June 11, 2008
Last Updated: March 16, 2011
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: Finnish Medicines Agency; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Additional relevant MeSH terms:

Diabetes Mellitus
Diabetes Mellitus, Type 2
Glucose Metabolism Disorders
Metabolic Diseases
Endocrine System Diseases
Glucagon-Like Peptide 1

Incretins
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Pharmacologic Actions

ClinicalTrials.gov processed this record on June 24, 2011

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A Trial in Type 2 Diabetes Comparing NN9535 to Placebo and Liraglutide

This study has been completed.

First Received: June 11, 2008 Last Updated: February 6, 2009 [History of Changes](#)

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00696657

Purpose

This trial is conducted in Africa, Asia and Europe. Subjects participating in this trial will be randomised to treatment with NN9535, placebo or liraglutide. Key efficacy parameter is HbA1c and the treatment duration is 12 weeks.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: NN9535 Drug: placebo Drug: liraglutide	Phase II

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

Official Title: A Dose Finding Trial Establishing Efficacy and Safety of NN9535 in Comparison With Placebo and Liraglutide in Type 2 Diabetes

Resource links provided by NLM:

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

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

[U.S. FDA Resources](#)

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Secondary Outcome Measures:

- Safety [Time Frame: for the duration of the trial] [Designated as safety issue: Yes]
- Antibodies [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Enrollment: 415
Study Start Date: June 2008
Study Completion Date: February 2009
Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental	Drug: NN9535 0.1 mg, once weekly, s.c. injection
B: Experimental	Drug: NN9535 0.2 mg, once weekly, s.c. injection
C: Experimental	Drug: NN9535 0.4 mg, once weekly, s.c. injection
D: Experimental	Drug: NN9535 0.8 mg, once weekly, s.c. injection
E: Experimental	Drug: NN9535 0.8 mg with titration, once weekly, s.c. injection
F: Experimental	Drug: NN9535 1.6 mg with titration, once weekly, s.c. injection
G1: Placebo Comparator	Drug: placebo 0.1 mg, once weekly, s.c. injection
G2: Placebo Comparator	Drug: placebo 0.2 mg, once weekly, s.c. injection
G3: Placebo Comparator	Drug: placebo 0.4 mg, once weekly, s.c. injection
G4: Placebo Comparator	Drug: placebo

	0.8 mg with titration, once weekly, s.c. injection
G5: Placebo Comparator	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G6: Placebo Comparator	Drug: placebo 1.6 mg, once weekly, s.c. injection
H: Experimental	Drug: liraglutide 1.2 mg with titration, once daily, s.c. injection
I: Experimental	Drug: liraglutide 1.8 mg with titration, once daily, s.c. injection

► Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Men and women-not-of-childbearing potential diagnosed with type 2 diabetes for at least three months
- Stable treatment regimen with either metformin (at least 1500 mg) or diet and exercise alone for at least three months
- HbA1c: 7.0-10.0 % (both inclusive)
- Body weight between 60 kg and 110 kg

Exclusion Criteria:

- Treatment with insulin, GLP-1 receptor agonists (including liraglutide), dipeptidyl peptidase-4 inhibitors, sulphonylurea, thiazolidinediones, Alpha-GIs, or any investigational drug, within the last three months
- Impaired liver or kidney function
- Proliferative retinopathy or maculopathy requiring acute treatment
- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension
- Recurrent major hypoglycaemia or hypoglycaemic unawareness
- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00696657

Locations

Austria

Wien, Austria, 1010

Bulgaria

Russe, Bulgaria, 7000

Finland

Oulu, Finland, 90029

France

MONTPELLIER cedex 5, France, 34295

Germany, LÄK Hessen

Pohlheim, LÄK Hessen, Germany, 35415

Hungary

Budapest, Hungary, H-1045

India, Tamil Nadu (INDIA)

Chennai, Tamil Nadu (INDIA), India, 600020

Italy, CH

Chieti Scalo, CH, Italy, 66013

Serbia

Belgrade, Serbia, 11000

South Africa, Cape Town

Observatory, Cape Town, South Africa, 7925

Spain

Almeria, Spain, 04001

Switzerland

Küsnacht, Switzerland, 8700

Turkey

Istanbul, Turkey, 34390

United Kingdom, East Sussex

Bexhill-on-Sea, East Sussex, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk

► More Information

Additional Information:

No publications provided

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
Study ID Numbers: NN9535-1821, EudraCT No: 2007-003956-12
Study First Received: June 11, 2008
Last Updated: February 6, 2009
ClinicalTrials.gov Identifier: [NCT00696657](#) [History of Changes](#)
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: National Agency for Medicines; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study placed in the following topic categories:

Signs and Symptoms
Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus

Endocrine System Diseases
Endocrinopathy
Glucose Metabolism Disorders
Metabolic Disorder

Additional relevant MeSH terms:

Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus
Endocrine System Diseases
Glucose Metabolism Disorders

ClinicalTrials.gov processed this record on September 01, 2009

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A Trial in Type 2 Diabetes Comparing NN9535 to Placebo and Liraglutide

This study has been completed.

First Received: June 11, 2008 Last Updated: February 6, 2009 [History of Changes](#)

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00696657

Purpose

This trial is conducted in Africa, Asia and Europe. Subjects participating in this trial will be randomised to treatment with NN9535, placebo or liraglutide. Key efficacy parameter is HbA1c and the treatment duration is 12 weeks.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: NN9535 Drug: placebo Drug: liraglutide	Phase II

MedlinePlus related topics: [Diabetes](#)

Drug Information available for: [Liraglutide](#)

U.S. FDA Resources

Study Type: Interventional

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

Official Title: A Dose Finding Trial Establishing Efficacy and Safety of NN9535 in Comparison With Placebo and Liraglutide in Type 2 Diabetes

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Secondary Outcome Measures:

- Safety [Time Frame: for the duration of the trial] [Designated as safety issue: Yes]
- Antibodies [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Enrollment: 415
Study Start Date: June 2008
Study Completion Date: February 2009
Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental	Drug: NN9535 0.1 mg, once weekly, s.c. injection
B: Experimental	Drug: NN9535 0.2 mg, once weekly, s.c. injection
C: Experimental	Drug: NN9535 0.4 mg, once weekly, s.c. injection
D: Experimental	Drug: NN9535 0.8 mg, once weekly, s.c. injection
E: Experimental	Drug: NN9535 0.8 mg with titration, once weekly, s.c. injection
F: Experimental	Drug: NN9535 1.6 mg with titration, once weekly, s.c. injection
G1: Placebo Comparator	Drug: placebo 0.1 mg, once weekly, s.c. injection
G2: Placebo Comparator	Drug: placebo 0.2 mg, once weekly, s.c. injection
G3: Placebo Comparator	Drug: placebo 0.4 mg, once weekly, s.c. injection
G4: Placebo Comparator	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G5: Placebo Comparator	Drug: placebo

	0.8 mg with titration, once weekly, s.c. injection
G6: Placebo Comparator	Drug: placebo 1.6 mg, once weekly, s.c. injection
H: Experimental	Drug: liraglutide 1.2 mg with titration, once daily, s.c. injection
I: Experimental	Drug: liraglutide 1.8 mg with titration, once daily, s.c. injection

► Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Men and women-not-of-childbearing potential diagnosed with type 2 diabetes for at least three months
- Stable treatment regimen with either metformin (at least 1500 mg) or diet and exercise alone for at least three months
- HbA1c: 7.0-10.0 % (both inclusive)
- Body weight between 60 kg and 110 kg

Exclusion Criteria:

- Treatment with insulin, GLP-1 receptor agonists (including liraglutide), dipeptidyl peptidase-4 inhibitors, sulphonylurea, thiazolidinediones, Alpha-GIs, or any investigational drug, within the last three months
- Impaired liver or kidney function
- Proliferative retinopathy or maculopathy requiring acute treatment
- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension
- Recurrent major hypoglycaemia or hypoglycaemic unawareness
- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00696657

Locations

Austria

Wien, Austria, 1010

Bulgaria

Russe, Bulgaria, 7000

Finland

Oulu, Finland, 90029

France

MONTPELLIER cedex 5, France, 34295

Germany, LÄK Hessen

Pohlheim, LÄK Hessen, Germany, 35415

Hungary

Budapest, Hungary, H-1045

India, Tamil Nadu (INDIA)

Chennai, Tamil Nadu (INDIA), India, 600020

Italy, CH

Chieti Scalo, CH, Italy, 66013

Serbia

Belgrade, Serbia, 11000

South Africa, Cape Town

Observatory, Cape Town, South Africa, 7925

Spain

Almeria, Spain, 04001

Switzerland

Küsnacht, Switzerland, 8700

Turkey

Istanbul, Turkey, 34390

United Kingdom, East Sussex

Bexhill-on-Sea, East Sussex, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk

► More Information

Additional Information:

[Clinical Trials at Novo Nordisk](#) EXT

At least 1000 needed

no publications provided

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
Study ID Numbers: NN9535-1821, EudraCT No: 2007-003956-12
Study First Received: June 11, 2008
Last Updated: February 6, 2009
ClinicalTrials.gov Identifier: [NCT00896657](#) [History of Changes](#)
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: National Agency for Medicines; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study placed in the following topic categories:

Signs and Symptoms
Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus

Endocrine System Diseases
Endocrinopathy
Glucose Metabolism Disorders
Metabolic Disorder

Additional relevant MeSH terms:

Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus
Endocrine System Diseases
Glucose Metabolism Disorders

ClinicalTrials.gov processed this record on May 07, 2009

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Home Search Study Topics Glossary

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A Trial in Type 2 Diabetes Comparing NN9535 to Placebo and Liraglutide

This study has been completed.

First Received: June 11, 2008 Last Updated: February 6, 2009 [History of Changes](#)

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00696657

Purpose

This trial is conducted in Africa, Asia and Europe. Subjects participating in this trial will be randomised to treatment with NN9535, placebo or liraglutide. Key efficacy parameter is HbA1c and the treatment duration is 12 weeks.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: NN9535 Drug: placebo Drug: liraglutide	Phase II

MedlinePlus related topics: [Diabetes](#)

Drug Information available for: [Liraglutide](#)

U.S. FDA Resources

Study Type: Interventional
Study Design: Treatment, Randomized, Double Blind (Subject, Investigator), Placebo Control, Parallel Assignment, Safety/Efficacy Study
Official Title: A Dose Finding Trial Establishing Efficacy and Safety of NN9535 in Comparison With Placebo and Liraglutide in Type 2 Diabetes

Further study details as provided by Novo Nordisk:

- Primary Outcome Measures:
- HbA1c [Time Frame: for the duration of the trial] [Designated as safety issue: No]
- Secondary Outcome Measures:
- Safety [Time Frame: for the duration of the trial] [Designated as safety issue: Yes]
 - Antibodies [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Enrollment: 415
Study Start Date: June 2008
Study Completion Date: February 2009
Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental	Drug: NN9535 0.1 mg, once weekly, s.c. injection
B: Experimental	Drug: NN9535 0.2 mg, once weekly, s.c. injection
C: Experimental	Drug: NN9535 0.4 mg, once weekly, s.c. injection
D: Experimental	Drug: NN9535 0.8 mg, once weekly, s.c. injection
E: Experimental	Drug: NN9535 0.8 mg with titration, once weekly, s.c. injection
F: Experimental	Drug: NN9535 1.6 mg with titration, once weekly, s.c. injection
G1: Placebo Comparator	Drug: placebo 0.1 mg, once weekly, s.c. injection
G2: Placebo Comparator	Drug: placebo 0.2 mg, once weekly, s.c. injection
G3: Placebo Comparator	Drug: placebo 0.4 mg, once weekly, s.c. injection
G4: Placebo Comparator	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G5: Placebo Comparator	Drug: placebo

no publications provided

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
Study ID Numbers: NN9535-1821, EudraCT No: 2007-003956-12
Study First Received: June 11, 2008
Last Updated: February 6, 2009
ClinicalTrials.gov Identifier: [NCT00696657](#) [History of Changes](#)
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: National Agency for Medicines; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study placed in the following topic categories:

Signs and Symptoms
Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus

Endocrine System Diseases
Endocrinopathy
Glucose Metabolism Disorders
Metabolic Disorder

Additional relevant MeSH terms:

Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus
Endocrine System Diseases
Glucose Metabolism Disorders

ClinicalTrials.gov processed this record on April 24, 2009

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Home Search Study Topics Glossary

Full Text View Tabular View Contacts and Locations No Study Results Posted Related Studies

A Trial in Type 2 Diabetes Comparing NN9535 to Placebo and Liraglutide

This study has been completed.

First Received: June 11, 2008 Last Updated: February 6, 2009 [History of Changes](#)

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00696657

Purpose

This trial is conducted in Africa, Asia and Europe. Subjects participating in this trial will be randomised to treatment with NN9535, placebo or liraglutide. Key efficacy parameter is HbA1c and the treatment duration is 12 weeks.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: NN9535 Drug: placebo Drug: liraglutide	Phase II

MedlinePlus related topics: [Diabetes](#)

Drug Information available for: [Liraglutide](#)

U.S. FDA Resources

Study Type: Interventional

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

Official Title: A Dose Finding Trial Establishing Efficacy and Safety of NN9535 in Comparison With Placebo and Liraglutide in Type 2 Diabetes

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Secondary Outcome Measures:

- Safety [Time Frame: for the duration of the trial] [Designated as safety issue: Yes]
- Antibodies [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Enrollment: 415
Study Start Date: June 2008
Study Completion Date: February 2009
Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental	Drug: NN9535 0.1 mg, once weekly, s.c. injection
B: Experimental	Drug: NN9535 0.2 mg, once weekly, s.c. injection
C: Experimental	Drug: NN9535 0.4 mg, once weekly, s.c. injection
D: Experimental	Drug: NN9535 0.8 mg, once weekly, s.c. injection
E: Experimental	Drug: NN9535 0.8 mg with titration, once weekly, s.c. injection
F: Experimental	Drug: NN9535 1.6 mg with titration, once weekly, s.c. injection
G1: Placebo Comparator	Drug: placebo 0.1 mg, once weekly, s.c. injection
G2: Placebo Comparator	Drug: placebo 0.2 mg, once weekly, s.c. injection
G3: Placebo Comparator	Drug: placebo 0.4 mg, once weekly, s.c. injection
G4: Placebo Comparator	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G5: Placebo Comparator	Drug: placebo

	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G6: Placebo Comparator	Drug: placebo 1.6 mg, once weekly, s.c. injection
H: Experimental	Drug: liraglutide 1.2 mg with titration, once daily, s.c. injection
I: Experimental	Drug: liraglutide 1.8 mg with titration, once daily, s.c. injection

► Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Men and women-not-of-childbearing potential diagnosed with type 2 diabetes for at least three months
- Stable treatment regimen with either metformin (at least 1500 mg) or diet and exercise alone for at least three months
- HbA1c: 7.0-10.0 % (both inclusive)
- Body weight between 60 kg and 110 kg

Exclusion Criteria:

- Treatment with insulin, GLP-1 receptor agonists (including liraglutide), dipeptidyl peptidase-4 inhibitors, sulphonylurea, thiazolidinediones, Alpha-GIs, or any investigational drug, within the last three months
- Impaired liver or kidney function
- Proliferative retinopathy or maculopathy requiring acute treatment
- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension
- Recurrent major hypoglycaemia or hypoglycaemic unawareness
- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00696657

Locations

Austria
Wien, Austria, 1010

Bulgaria
Russe, Bulgaria, 7000

Finland
Oulu, Finland, 90029

France
MONTPELLIER cedex 5, France, 34295

Germany, LÄK Hessen
Pohlheim, LÄK Hessen, Germany, 35415

Hungary
Budapest, Hungary, H-1045

India, Tamil Nadu (INDIA)
Chennai, Tamil Nadu (INDIA), India, 600020

Italy, CH
Chieti Scalo, CH, Italy, 66013

Serbia
Belgrade, Serbia, 11000

South Africa, Cape Town
Observatory, Cape Town, South Africa, 7925

Spain
Almeria, Spain, 04001

Switzerland
Küsnacht, Switzerland, 8700

Turkey
Istanbul, Turkey, 34390

United Kingdom, East Sussex
Bexhill-on-Sea, East Sussex, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk

► More Information

Additional Information:

[Clinical Trials at Novo Nordisk](#) 

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no publications provided

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
Study ID Numbers: NN9535-1821, EudraCT No: 2007-003956-12
Study First Received: June 11, 2008
Last Updated: February 6, 2009
ClinicalTrials.gov Identifier: [NCT00696657](#) [History of Changes](#)
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: National Agency for Medicines; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study placed in the following topic categories:

Signs and Symptoms
Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus

Endocrine System Diseases
Endocrinopathy
Glucose Metabolism Disorders
Metabolic Disorder

Additional relevant MeSH terms:

Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus
Endocrine System Diseases
Glucose Metabolism Disorders

ClinicalTrials.gov processed this record on March 26, 2009

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<http://web.archive.org/web/20090116023043/https://clinicaltrials.gov/ct2/show/NCT00696657>

A Trial in Type 2 Diabetes Comparing NN9535 to Placebo and Liraglutide

This study is ongoing, but not recruiting participants.

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00696657

Purpose

This trial is conducted in Africa, Asia and Europe. Subjects participating in this trial will be randomised to treatment with NN9535, placebo or liraglutide. Key efficacy parameter is HbA1c and the treatment duration is 12 weeks.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: NN9535 Drug: placebo Drug: liraglutide	Phase II

MedlinePlus related topics: [Diabetes](#)

Drug Information available for: [Liraglutide](#)

U.S. FDA Resources

Study Type: Interventional

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

Official Title: A Dose Finding Trial Establishing Efficacy and Safety of NN9535 in Comparison With Placebo and Liraglutide in Type 2 Diabetes

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Secondary Outcome Measures:

- Safety [Time Frame: for the duration of the trial] [Designated as safety issue: Yes]
- Antibodies [Time Frame: for the duration of the trial] [Designated as safety issue: No]

Estimated Enrollment: 362

Study Start Date: June 2008

Estimated Study Completion Date: February 2009

Estimated Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental	Drug: NN9535 0.1 mg, once weekly, s.c. injection
B: Experimental	Drug: NN9535 0.2 mg, once weekly, s.c. injection
C: Experimental	Drug: NN9535 0.4 mg, once weekly, s.c. injection
D: Experimental	Drug: NN9535 0.8 mg, once weekly, s.c. injection
E: Experimental	Drug: NN9535 0.8 mg with titration, once weekly, s.c. injection
F: Experimental	Drug: NN9535 1.6 mg with titration, once weekly, s.c. injection
G1: Placebo Comparator	Drug: placebo 0.1 mg, once weekly, s.c. injection
G2: Placebo Comparator	Drug: placebo 0.2 mg, once weekly, s.c. injection
G3: Placebo Comparator	Drug: placebo 0.4 mg, once weekly, s.c. injection
G4: Placebo Comparator	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G5: Placebo Comparator	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection

G6: Placebo Comparator	Drug: placebo 1.6 mg, once weekly, s.c. injection
H: Experimental	Drug: liraglutide 1.2 mg with titration, once daily, s.c. injection
I: Experimental	Drug: liraglutide 1.8 mg with titration, once daily, s.c. injection

► Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Men and women-not-of-childbearing potential diagnosed with type 2 diabetes for at least three months
- Stable treatment regimen with either metformin (at least 1500 mg) or diet and exercise alone for at least three months
- HbA1c: 7.0-10.0 % (both inclusive)
- Body weight between 60 kg and 110 kg

Exclusion Criteria:

- Treatment with insulin, GLP-1 receptor agonists (including liraglutide), dipeptidyl peptidase-4 inhibitors, sulphonylurea, thiazolidinediones, Alpha-GIs, or any investigational drug, within the last three months
- Impaired liver or kidney function
- Proliferative retinopathy or maculopathy requiring acute treatment
- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension
- Recurrent major hypoglycaemia or hypoglycaemic unawareness
- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00696657

Locations

Austria
Wien, Austria, 1010

Bulgaria
Russe, Bulgaria, 7000

Finland
Oulu, Finland, 90029

France
MONTPELLIER cedex 5, France, 34295

Germany, LÄK Hessen
Pohlheim, LÄK Hessen, Germany, 35415

Hungary
Budapest, Hungary, H-1045

India, Tamil Nadu (INDIA)
Chennai, Tamil Nadu (INDIA), India, 600020

Italy, CH
Chieti Scalo, CH, Italy, 66013

Serbia
Belgrade, Serbia, 11000

South Africa, Cape Town
Observatory, Cape Town, South Africa, 7925

Spain
Almeria, Spain, 04001

Switzerland
Küsnacht, Switzerland, 8700

Turkey
Istanbul, Turkey, 34390

United Kingdom, East Sussex
Bexhill-on-Sea, East Sussex, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk

► More Information

[Clinical Trials at Novo Nordisk](#) external link

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
 Study ID Numbers: NN9535-1821, EudraCT No: 2007-003956-12
 Study First Received: June 11, 2008
 Last Updated: January 14, 2009

Last updated: January 14, 2009

ClinicalTrials.gov Identifier: [NCT00696657](#) [\[history\]](#)

Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: National Agency for Medicines; France: Afssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: Ministry of Health; Italy: National Monitoring Centre for Clinical Trials - Ministry of Health; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study placed in the following topic categories:

Signs and Symptoms
Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus

Endocrine System Diseases
Endocrinopathy
Metabolic disorder
Glucose Metabolism Disorders

ClinicalTrials.gov processed this record on January 15, 2009

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A Trial in Type 2 Diabetes Comparing NN9535 to Placebo and Liraglutide

This study is ongoing, but not recruiting participants.

Sponsored by:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00696657

Purpose

This trial is conducted in Africa, Asia and Europe. Subjects participating in this trial will be randomised to treatment with NN9535, placebo or liraglutide. Key efficacy parameter is HbA1c and the treatment duration is 12 weeks.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: NN9535 Drug: placebo Drug: liraglutide	Phase II

MedlinePlus related topics: [Diabetes](#)

Drug Information available for: [Liraglutide](#)

U.S. FDA Resources

Study Type: [Interventional](#)

Study Design: [Treatment, Randomized, Double Blind \(Subject, Investigator\), Placebo Control, Parallel Assignment, Safety/Efficacy Study](#)

Official Title: [A Dose Finding Trial Establishing Efficacy and Safety of NN9535 in Comparison With Placebo and Liraglutide in Type 2 Diabetes](#)

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- HbA1c [Time Frame: For the duration of the trial] [Designated as safety issue: No]

Secondary Outcome Measures:

- Safety [Time Frame: For the duration of the trial] [Designated as safety issue: Yes]
- Antibodies [Time Frame: For the duration of the trial] [Designated as safety issue: No]

Estimated Enrollment:

362

Study Start Date:

June 2008

Estimated Study Completion Date:

February 2009

Estimated Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental	Drug: NN9535 0.1 mg, once weekly, s.c. injection
B: Experimental	Drug: NN9535 0.2 mg, once weekly, s.c. injection
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G4: Placebo Comparator	Drug: placebo 0.8 mg with titration, once weekly, s.c. injection
G5: Placebo Comparator	Drug: placebo

	0.8 mg with titration, once weekly, s.c. injection
G6: Placebo Comparator	Drug: placebo 1.6 mg, once weekly, s.c. injection
H: Experimental	Drug: liraglutide 1.2 mg with titration, once daily, s.c. injection
I: Experimental	Drug: liraglutide 1.8 mg with titration, once daily, s.c. injection

► Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Men and women-not-of-childbearing potential diagnosed with type 2 diabetes for at least three months
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- Treatment with insulin, GLP-1 receptor agonists (including liraglutide), dipeptidyl peptidase-4 inhibitors, sulphonylurea, thiazolidinediones, Alpha-GIs, or any investigational drug, within the last three months
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- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00696657

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Finland

Oulu, Finland, 90029

France

MONTPELLIER cedex 5, France, 34295

Germany, LÄK Hessen

Pohlheim, LÄK Hessen, Germany, 35415

Hungary

Budapest, Hungary, H-1045

India, Tamil Nadu (INDIA)

Chennai, Tamil Nadu (INDIA), India, 600020

Italy, CH

Chieti Scalo, CH, Italy, 66013

Serbia

Belgrade, Serbia, 11000

South Africa, Cape Town

Observatory, Cape Town, South Africa, 7925

Spain

Almeria, Spain, 04001

Switzerland

Küsnacht, Switzerland, 8700

Turkey

Istanbul, Turkey, 34390

United Kingdom, East Sussex

Bexhill-on-Sea, East Sussex, United Kingdom, TN39 4SP

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Christine B. Jensen, MD, PhD Novo Nordisk A/S

► More Information

[Clinical Trials at Novo Nordisk](#) C01

Responsible Party: Novo Nordisk A/S (Public Access to Clinical Trials)
Study ID Numbers: NN9535-1821, EudraCT No: 2007-003956-12
First Received: June 11, 2008
Last Updated: October 16, 2008
ClinicalTrials.gov Identifier: [NCT00696657](#)
Health Authority: Austria: Federal Ministry for Health and Women; Bulgaria: Bulgarian Drug Agency; Finland: National Agency for Medicines; France: Atssaps - French Health Products Safety Agency; Germany: Federal Institute for Drugs and Medical Devices; Hungary: National Institute of Pharmacy; India: India's Drug Controller General, a division of the Ministry of; Italy: National Monitoring Centre for Clinical Trials - Ministry of He; Serbia: Medicines and Medical Devices Agency of Serbia; South Africa: Medicines Control Council; Spain: Spanish Agency of Medicines; Switzerland: Laws and standards; Turkey: Ministry of Health; United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study placed in the following topic categories:

Signs and Symptoms
Metabolic Diseases
Diabetes Mellitus, Type 2
Diabetes Mellitus

Endocrine System Diseases
Endocrinopathy
Metabolic disorder
Glucose Metabolism Disorders

ClinicalTrials.gov processed this record on October 28, 2008

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