INTERNET ARCHIVE
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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 The visitor may select one of those dates, and begin browsing an archived version of the Web.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 For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file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.

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

DATE: 02/19/2023

Nathaniel Frank-White

Nathaniel E Frank-White

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EXHIBIT A

INTERNET ARCHIVE WaybackMachine https://clinicaltrials.gov/ct2/show/NCT00851773 Go OCT DEC SEP 27 2009 2011 2013 About this capture
10 captures
11 Sep 2009 - 16 Apr 2021

Safety, Tolerability, and Profile of Action of Drug in the Body of NN9535 in Healthy Male Japanese and Caucasian Subjects

This study has been completed.

Study NCT00851773 Information provided by Novo Nordisk
First Received: February 25, 2009 Last Updated: July 15, 2010 History of Changes

No Study Results Posted on ClinicalTrials.gov for this Study

About Study Results Reporting on ClinicalTrials.gov

Study Status:	This study has been completed.
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Contact Help Desk
Lister Hill National Center for Biomedical Communications, U.S. National Library of Medicine,
U.S. National Institutes of Health, U.S. Department of Health & Human Services,
USA.gov, Copyright, Privacy, Accessibility, Freedom of Information Act

INTERNET ARCHIVE WaybackMachine https://clinicaltrials.gov/ct2/show/NCT00851773 Go SEP OCT DEC 22 2009 2011 2012 About this capture
10 captures
11 Sep 2009 - 16 Apr 2021

Safety, Tolerability, and Profile of Action of Drug in the Body of NN9535 in Healthy Male Japanese and Caucasian Subjects

This study has been completed.

First Received on February 25, 2009. Last Updated on July 15, 2010 History of Changes

Sponsor:	Novo Nordisk
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00851773

Purpose

This trial is conducted in Europe. The aim of this clinical trial is to assess and compare the safety and tolerability, as assessed by adverse events after multiple subcutaneous doses of NN9535 in healthy male Japanese and Caucasian subjects.

Condition	Intervention	Phase
Healthy	Drug: NN9535 Drug: placebo	Phase I

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

Official Title: A Randomised, Double Blind, Placebo-controlled, Parallel-group, Multiple Doses, Dose Escalation Study to Assess the Safety, Tolerability, and Pharmacokinetics Profiles of NN9535 in Healthy Male Japanese and Caucasian Subjects After Weekly Subcutaneous Injections.

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- Adverse events [Time Frame: at all scheduled visits (2 - 14) following screening] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Frequency of hypoglycaemic episodes [Time Frame: at all scheduled visits (2 - 14) following screening] [Designated as safety issue: Yes]
- Vital signs (blood pressure and pulse) [Time Frame: at all scheduled visits (2 - 14) including screening (visit 1)] [Designated as safety issue: No]
- 12-lead ECG (electrocardiogram) [Time Frame: at all scheduled visits (2 - 14) including screening (visit 1)] [Designated as safety issue: No]
- Haematology [Time Frame: at all scheduled visits (2 - 14) including screening (visit 1)] [Designated as safety issue: No]
- Biochemistry [Time Frame: at all scheduled visits (2 - 14) including screening (visit 1)] [Designated as safety issue: No]
- Urinalysis [Time Frame: at all scheduled visits (2 - 14) including screening (visit 1)] [Designated as safety issue: No]
- Calcitonin [Time Frame: at screening (visit 1) and at visits 2, 9 and 14] [Designated as safety issue: No]
- Antibody development against N9535 [Time Frame: at visits 2 and 14] [Designated as safety issue: No]

Enrollment: 84
Study Start Date: February 2009
Study Completion Date: October 2009
Primary Completion Date: October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
A: Experimental Intervention: Drug: NN9535	Drug: NN9535 0.1 mg once weekly, s.c. injection
B: Experimental Intervention: Drug: NN9535	Drug: NN9535 0.2 mg once weekly, s.c. injection
C: Experimental Intervention: Drug: NN9535	Drug: NN9535 0.4 mg once weekly, s.c. injection
D: Experimental Intervention: Drug: NN9535	Drug: NN9535 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 7 weeks, s.c. injection
E: Experimental Intervention: Drug: NN9535	Drug: NN9535 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 1 week, 1.2 mg once weekly for 6 weeks, s.c. injection
F1: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.1 mg once weekly, s.c. injection

F2: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.2 mg once weekly, s.c. injection
F3: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.4 mg once weekly, s.c. injection
F4: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 7 weeks, s.c. injection
F5: Placebo Comparator Intervention: Drug: placebo	Drug: placebo 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 1 week, followed by 1.2 mg once weekly injections for 6 weeks, s.c. injection

Eligibility

Ages Eligible for Study: 20 Years to 45 Years
Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- For Caucasian or Japanese volunteers the following applies:
- Informed consent obtained before any trial-related activities
- Body weight between 54 and 90 kg (both inclusive)
- Body mass index (BMI) between 18.5 and 24.9 kg/m2 (both inclusive)
- HbA1c below 6.0 %
- Subjects who are considered to be generally healthy based on assessment of medical history, physical examination and clinical laboratory data at screening, as judged by the Investigator
- Subjects who are sexually active and have partners who are or could be pregnant are willing and required to use a barrier method of contraception (e.g. condom) for the duration of the study and for 90 days following the last dose of study medication
- Japanese passport holder, Japanese-born parents, lived outside Japan for 5 years or less

Exclusion Criteria:

- Any clinical laboratory values deviating from or outside the laboratory reference range unless considered not to be clinically significant by the investigator
- Any abnormal ECG findings at the screening, considered to be clinically significant by the Investigator
- Presence or history of diabetes, cancer or any clinically significant cardiac, respiratory, metabolic, renal, hepatic, gastrointestinal, endocrinological, dermatological, venereal, haematological, neurological, or psychiatric diseases or disorders, considered to be clinically significant by the Investigator
- Previous randomised in this trial (not applicable for stand-by volunteers)
- Blood pressure in supine position at the screening, after resting for 5 min, and in the standing position after standing for 1 min, consistently outside the ranges 90 - 140 mmHg systolic or 40 - 90 mmHg diastolic
- Heart rate in supine position at the screening, after resting for 5 min, consistently above 100 beats/min
- Alcohol intake within 48 hours prior to the screening and admission (examined by alcohol breath test)
- Hepatitis B surface antigen, Hepatitis C antibodies or Human Immunodeficiency Virus (HIV) antibodies positive
- History of significant allergy or hypersensitivity
- Known or suspected allergy to trial product or related products
- History of drug or alcohol abuse (alcohol abuse is defined as intake of more than 21 units (U) weekly: One unit of alcohol equals 1/2 pint (approximately 250 mL) of beer or lager, or one glass of wine or Japanese sake, or 1/6 gill (approximately 20 mL) of spirits)
- Subjects who smoke more than 10 cigarettes, or the equivalent, per day or is unwilling to refrain from smoking whenever required for the trial procedure
- Use of prescription drugs within 3 weeks prior to dosing, non-prescription drugs within 1 week prior to dosing except for vitamins, minerals and nutritional supplements
- Received any investigational drug within 12 weeks prior to the planned first dosing
- Subjects who have taken part in strenuous exercise within 48 hours prior to first dosing, due to interference with the hepatic microsomal monooxygenase system. The Investigator or Sub-Investigator will evaluate whether strenuous exercise has been undertaken
- Loss of more than 400 mL blood in total within the last 12 weeks or more than 200 mL blood in total within the last 4 weeks prior to first dosing
- Subjects with a first-degree relative with diabetes mellitus
- Mental incapacity, unwillingness or language barriers precluding adequate understanding or cooperation
- Possibility that the subject will not comply with the protocol
- Subjects who in the opinion of the Investigator or Sub-Investigator should not participate in the trial
- Subjects with known history of either Type 1 or Type 2 diabetes mellitus are excluded

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00851773

Locations

United Kingdom
London SW, United Kingdom, 17 0RE

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Jan Lynge, MSc, PhD Novo Nordisk

More Information

Additional Information:

Clinical Trials at Novo Nordisk

No publications provided

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

ClinicalTrials.gov Identifier: NCT00851773 History of Changes
Other Study ID Numbers: NN9535-3633, 2008-006325-13
Study First Received: February 25, 2009
Last Updated: July 15, 2010
Health Authority: United Kingdom: Medicines and Healthcare Products Regulatory Agency

ClinicalTrials.gov processed this record on October 20, 2011

Contact Help Desk
Lister Hill National Center for Biomedical Communications, U.S. National Library of Medicine,
U.S. National Institutes of Health, U.S. Department of Health & Human Services,
USA.gov. Copyright. Privacy. Accessibility. Freedom of Information Act

INTERNET ARCHIVE Wayback Machine https://clinicaltrials.gov/ct2/show/NCT00851773 Go AUG SEP OCT 11 2008 2009 2011 About this capture
10 captures
11 Sep 2009 - 16 Apr 2021

Safety, Tolerability, and Profile of Action of Drug in the Body of NN9535 in Healthy Male Japanese and Caucasian Subjects

This study is ongoing, but not recruiting participants.

First Received: February 25, 2009 Last Updated: August 26, 2009 History of Changes

Sponsored by:	**Novo Nordisk**
Information provided by:	Novo Nordisk
ClinicalTrials.gov Identifier:	NCT00851773

Purpose

This trial is conducted in Europe. The aim of this clinical trial is to assess and compare the safety and tolerability, as assessed by adverse events after multiple subcutaneous doses of NN9535 in healthy male Japanese and Caucasian subjects.

Condition	Intervention	Phase
Healthy	Drug: NN9535 Drug: placebo	Phase I

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

Official Title: A Randomised, Double Blind, Placebo-controlled, Parallel-group, Multiple Doses, Dose Escalation Study to Assess the Safety, Tolerability, and Pharmacokinetics Profiles of NN9535 in Healthy Male Japanese and Caucasian Subjects After Weekly Subcutaneous Injections.

Further study details as provided by Novo Nordisk:

Primary Outcome Measures:

- Adverse events [Time Frame: at all scheduled visits (2 - 14) following screening] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Frequency of hypoglycaemic episodes [Time Frame: at all scheduled visits (2 - 14) following screening] [Designated as safety issue: Yes]
- Vital signs (blood pressure and pulse) [Time Frame: at all scheduled visits (2 - 14) including screening (visit 1)] [Designated as safety issue: No]
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- Antibody development against N9535 [Time Frame: at visits 2 and 14] [Designated as safety issue: No]

Enrollment: 84
Study Start Date: February 2009
Estimated Study Completion Date: August 2009
Estimated Primary Completion Date: August 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 0.4 mg once weekly for 1 week, 0,8 mg once weekly for 7 weeks, s.c. injection
E: Experimental	Drug: NN9535 0.8 mg once weekly, s.c. injection
F: Experimental	Drug: NN9535 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 1 week, 1.6 mg once weekly for 6 weeks, s.c. injection
G: Experimental	Drug: NN9535 S.c. injection: 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 1 week, followed by once weekly injections for 6 weeks. Dose to be determined based on safety and tolerability of previous dose steps. This dose-arm is optional and will only be implemented if the 0.8 mg is tolerated but the 1.6 mg is not.
H1: Placebo Comparator	Drug: placebo 0.1 mg once weekly, s.c. injection

H2: Placebo Comparator	Drug: placebo 0.2 mg once weekly, s.c. injection
H3: Placebo Comparator	Drug: placebo 0.4 mg once weekly, s.c. injection
H4: Placebo Comparator	Drug: placebo 0.4 mg once weekly for 1 week, 0,8 mg once weekly for 7 weeks, s.c. injection
H5: Placebo Comparator	Drug: placebo 0.8 mg once weekly, s.c. injection
H6: Placebo Comparator	Drug: placebo 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 1 week, 1.6 mg once weekly for 6 weeks, s.c. injection
H7: Placebo Comparator	Drug: placebo S.c. injection: 0.4 mg once weekly for 1 week, 0.8 mg once weekly for 1 week, followed by once weekly injections for 6 weeks. Dose to be determined based on safety and tolerability of previous dose steps.

Eligibility

Ages Eligible for Study: 20 Years to 45 Years
Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- For Caucasian or Japanese volunteers the following applies:
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- Subjects who are sexually active and have partners who are or could be pregnant are willing and required to use a barrier method of contraception (e.g. condom) for the duration of the study and for 90 days following the last dose of study medication
- Japanese passport holder, Japanese-born parents, lived outside Japan for 5 years or less

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- Presence or history of diabetes, cancer or any clinically significant cardiac, respiratory, metabolic, renal, hepatic, gastrointestinal, endocrinological, dermatological, venereal, haematological, neurological, or psychiatric diseases or disorders, considered to be clinically significant by the Investigator
- Previous randomised in this trial (not applicable for stand-by volunteers)
- Blood pressure in supine position at the screening, after resting for 5 min, and in the standing position after standing for 1 min, consistently outside the ranges 90 - 140 mmHg systolic or 40 - 90 mmHg diastolic
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- Subjects who smoke more than 10 cigarettes, or the equivalent, per day or is unwilling to refrain from smoking whenever required for the trial procedure
- Use of prescription drugs within 3 weeks prior to dosing, non-prescription drugs within 1 week prior to dosing except for vitamins, minerals and nutritional supplements
- Received any investigational drug within 12 weeks prior to the planned first dosing
- Subjects who have taken part in strenuous exercise within 48 hours prior to first dosing, due to interference with the hepatic microsomal monooxygenase system. The Investigator or Sub-Investigator will evaluate whether strenuous exercise has been undertaken
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- Subjects with a first-degree relative with diabetes mellitus
- Mental incapacity, unwillingness or language barriers precluding adequate understanding or cooperation
- Possibility that the subject will not comply with the protocol
- Subjects who in the opinion of the Investigator or Sub-Investigator should not participate in the trial
- Subjects with known history of either Type 1 or Type 2 diabetes mellitus are excluded

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00851773

Locations

United Kingdom
London SW, United Kingdom, 17 0RE

Sponsors and Collaborators

Novo Nordisk

Investigators

Study Director: Jan Lynge, MSc,PhD Novo Nordisk

More Information

Additional 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:	NN9535-3633, EudraCT No: 2008-006325-13
Study First Received:	February 25, 2009
Last Updated:	August 26, 2009
ClinicalTrials.gov Identifier:	NCT00851773 History of Changes
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study placed in the following topic categories:
Healthy

ClinicalTrials.gov processed this record on September 10, 2009

Contact Help Desk
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U.S. National Institutes of Health, U.S. Department of Health & Human Services,
USA.gov, Copyright, Privacy, Accessibility, Freedom of Information Act

JURAT ATTACHMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF Virginia }

COUNTY OF Arlington }

The foregoing instrument was subscribed and sworn before me this date of 02/19/2023, by Nathaniel Frank-White

This notarial act was an online notarization.

CHIRAG PATEL
ELECTRONIC NOTARY PUBLIC
COMMONWEALTH OF VIRGINIA
NOTARY ID: 7679556
COMISSION EXP: JUNE 30, 2024

(Notary Seal)

Notary's Signature

Registration No.: 7679556

Commission Expiration Date: June 30, 2024