A TRIAL TO COMPARE THE INJECTION SITE PAIN EXPERIENCE OF 0.25 MG SEMAGLUTIDE SC ADMINISTERED BY 2 DIFFERENT PRODUCTS

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The primary objective is to compare, in healthy subjects, the injection site experience of a single dose of 0.25 mg semaglutide sc, given as the DV3396 product to that of the PDS290 product.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48226

Source
ToetsingOnline

Brief title
SDD injection pain experience trial

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes

Health condition

Overweight, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Novo Nordisk
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Injection, Semaglutide, Site Experience

Outcome measures

Primary outcome

Intensity of injection site pain

Secondary outcome

Exploratory endpoints:

Categorical assessment of injection site pain

More than moderate injection site pain

Quality of pain

Duration of pain

Comparative pain experience

The DV3396 product hurt less than or about the same as the PDS290 product

Study description

Background summary

People with diabetes have high amounts of sugar in their blood and need treatment to control their sugar level. Semaglutide is a newly approved antidiabetic medicine that helps to lower blood sugar levels in patients with type 2 diabetes. Semaglutide is injected under the skin. Semaglutide is injected under the skin with a, so called, injection pen. In this study the pain around the injection site will be compared after administration of 2

different solutions of semaglutide. Both injection pens will contain the same amount of semaglutide, but the fluid in which the drug is dissolved in is different.

Study objective

The primary objective is to compare, in healthy subjects, the injection site experience of a single dose of 0.25 mg semaglutide sc, given as the DV3396 product to that of the PDS290 product.

Study design

The actual study will consist of 1 day during which the subjects will stay in the research center for about 6 hours.

Intervention

Semaglutide (0.25 mg) will be given twice as an injection under the skin (subcutaneous), once on the left side and once on the right side of the belly. There will be a minimum of 30 minutes between the 2 injections. After each injection the subjects are asked to fill in questionnaires about the level of pain they experience around the injection site after the injection (so not the pain of the injection itself).

During the 30 minutes after each administration of the study compound the subjects should stay in bed or should be seated in a chair, and not walk around.

The subjects are blindfolded during the administration of the study compound so they cannot see which injection pen was used. Only the person who will inject will know which pen was used on which side of the belly. The person who will give the questionnaires also does not know which injection pen was used.

Study burden and risks

The study compound may cause side effects.

Semaglutide has been extensively studies in healthy volunteer. diabetic and obese patients. The following side effects are most frequently observed (in more than 1 out of 10 people):
Stomach and gut problems. Signs may include:
•feeling sick (*nausea*) or being sick (*vomiting*)
•diarrhea (loose, watery and more frequent stools)
•upset stomach and constipation
•Low appetite
•Pain in your stomach area

The study compound may also have side effects that are still unknown.

Drawing blood may be painful or cause some bruising.
In total, we will take about 40 milliliters (mL) of blood.
To make a heart tracing, electrodes (small, plastic patches) will be pasted at specific locations on your arms, chest and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Contacts

Public
Novo Nordisk

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male or female subjects, aged 18 to 75 years (both inclusive) at the time of signing informed consent
- Body mass index (BMI) equal to or above 25.0 kg/m^2

- Considered to be generally healthy based on the medical history, physical examination, and the results of vital signs, electrocardiogram (ECG), and clinical laboratory tests performed during the screening visit, as judged by the Investigator

Exclusion criteria

- Woman who is pregnant or breast-feeding or intends to become pregnant within 4 weeks after administration of the study drug, or is of childbearing potential and not using highly effective contraceptive methods with her fertile male sexual partner
- Any disorder that in the Investigator's opinion might jeopardize subject's safety, evaluation of results, or compliance with the protocol
- Glycosylated hemoglobin >=6.5% at screening
- Use of prescription medicinal products or non-prescription drugs or herbal products, except routine vitamins, topical medication, contraceptives, and occasional use of paracetamol (paracetamol not allowed within 24 hours prior to drug administration), within 14 days prior to drug administration
- Average intake of more than 21 units of alcohol per week for male subjects and more than 14 units per week for female subjects: 1 unit of alcohol equals approximately 250 mL of beer, 100 mL of wine, or 35 mL of spirits
- Positive drug and alcohol screen (opiates, methadone, cocaine, amphetamines [including ecstasy], cannabinoids, barbiturates, benzodiazepines, tricyclic antidepressants, and alcohol) at screening and admission to the clinical research center
- Use of tobacco and nicotine products, defined as any of the below:
a) Smoking more than 1 cigarette or the equivalent per day on average
b) Not able or willing to refrain from smoking and the use of nicotine substitute products during the inhouse period
- Subject is not able to understand and read English or Dutch, or subject is not able to understand and comply with the study requirements

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2019
Enrollment:	104
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N/A
Generic name:	Semaglutide
Product type:	Medicine
Brand name:	Ozempic
Generic name:	Semaglutide
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	24-06-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	25-06-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	U1111-1233-9590
EudraCT	EUCTR2019-002284-10-NL
CCMO	NL70376.056.19