# A TRIAL TO COMPARE THE INJECTION SITE PAIN EXPERIENCE OF SEMAGLUTIDE 0.25 MG AND DULAGLUTIDE 0.75 MG ADMINISTERED SC

Published: 19-11-2019
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The purpose of this study is to investigate if there is a difference in the injection site pain experience after an injection under the skin (subcutaneous) with 2 different products, semaglutide and dulaglutide, in healthy volunteers. The 2 products...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON48004

**Source**
ToetsingOnline

**Brief title**
Injection site pain experience of semaglutide and dulaglutide sc

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
Diabetes

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Novo Nordisk A/S

**Source(s) of monetary or material Support:** Pharmaceutical Industry

## Intervention

**Keyword:** Dulaglutide, Injection, Pain experience, Semaglutide

## 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

# Study description

### Background summary

People with diabetes have too much sugar in their blood and need treatment to control their sugar level. Semaglutide and dulaglutide are approved medicines that help to lower blood sugar levels in patients with type 2 diabetes. Semaglutide and dulaglutide are injected under the skin with an injection pen. In this study the pain experience around the injection site will be compared after administration of semaglutide and dulaglutide in 2 different injection pens.

### Study objective

The purpose of this study is to investigate if there is a difference in the injection site pain experience after an injection under the skin (subcutaneous) with 2 different products, semaglutide and dulaglutide, in healthy volunteers.

The 2 products will be injected with 2 different injection pens.

**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) and dulaglutide (0.75 mg) will be given as injections under the skin of the belly. After each injection subjects are asked to fill in questionnaires about the level and type of pain they may experience around the injection site during and after the injection.

**Study burden and risks**

Semaglutide
Semaglutide has been extensively studied in healthy volunteers. diabetic and obese patients. The following side effects are very common (may affect more than 1 in 10 people ):
• feeling sick (*nausea*)
• diarrhea (loose, watery and more frequent stools)
These side effects most often happen at the start of the treatment and are usually mild to moderate in severity

Dulaglutide
The study compound may cause side effects.
The following side effects are very common (may affect more than 1 in 10 people):
• feeling sick (*nausea*)
• being sick (*vomiting*)
• diarrhea (loose, watery and more frequent stools)
• abdominal (stomach) pain
These side effects are usually not severe. They are most common when first starting dulaglutide but decrease over time in most subjects.

The study compounds may also have side effect 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 pat chest) will be pasted at specific locations on the arms, chest and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

# Contacts

**Public**
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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, aged 18-75 years (both inclusive) at the time of signing informed consent.
- Body mass index >=25.0 kg/m2.
- Considered to be generally healthy based on the medical history, physical examination, and the results of vital signs, electrocardiogram and clinical laboratory tests performed during the screening visit, as judged by the Investigator.

## Exclusion criteria

- Female who is pregnant, breast-feeding or intends to become pregnant within 4

weeks of Day 1 or is of childbearing potential and not using highly effective contraceptive methods.
- Any disorder which in the Investigator*s opinion might jeopardise subject*s safety, evaluation of results, or compliance with the protocol.
- Glycosylated hemoglobin (HbA1c) >= 6.5 % (48 mmol/mol) 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 (not allowed within 24 hours prior to drug administration), within 14 days prior to Day 1.
- 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.
- Use of tobacco and nicotine products, defined as any of the below:
o Smoking more than 1 cigarette or the equivalent per day on average.
o Not able or willing to refrain from smoking and use of nicotine substitute products during the in-house 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

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|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Double blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-12-2019 |
| Enrollment: | 104 |

| | |
|---|---|
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Ozempic |
| Generic name: | Semaglutide |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Trulicity |
| Generic name: | Dulaglutide |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 19-11-2019 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 26-11-2019 |
| 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 |
| --- | --- |
| EudraCT | EUCTR2019-83003844--NL |
| CCMO | NL71900.056.19 |