

## Summary of the results of the clinical trial for laypersons

# A research study comparing the amount of active drug in the blood of healthy people after taking 2 different types of semaglutide tablets

## About this summary

This summary gives the public information about a research study called a 'clinical trial'. It is also written for people who took part in the study.

The full results of the research study are described in a long report - for researchers, health professionals and for people who approve medicines. This document is a summary of that report.

These results are for this study only. Other studies may show different results.

Thank you to the people who took part in the study and staff who made this study possible.

## 1 General information about the study

### When and where did the study take place?

The study took place from October 2019 to January 2021 in Germany.

Several measures were put in place to protect people in the study from getting infected with the novel corona virus (COVID-19). There was also a temporary break in the study due to the COVID-19 pandemic.

This did not impact the overall study completeness and results.

### Why is this study important?

People with type 2 diabetes have high blood sugar levels. Too high blood sugar can be harmful to the body.

Controlling blood sugar is important for managing type 2 diabetes. Diet and exercise are common ways to help control blood sugar. When diet and exercise are not enough, doctors prescribe medicines to help control blood sugar.

Semaglutide in a tablet form is a new medicine for treating people with type 2 diabetes. The semaglutide tablet is available in many countries.

The semaglutide tablet (current formulation) also contains a product called SNAC that helps the body absorb semaglutide from the stomach. Along with semaglutide and SNAC, there are three additional 'helping agents' in the tablet that release the medicine from the tablet in the body.

Researchers think that changing the levels of the helping agents in semaglutide tablet may affect how much of the medicine the body takes up.

A new formulation, called semaglutide C tablet, contains fewer helping agents.

This study was conducted to compare the semaglutide C tablet with the semaglutide tablet.

### What did researchers want to find out?

Researchers wanted to find out if the amount of semaglutide in the tablet can be lowered and if it affects the amount of semaglutide reaching people's blood.

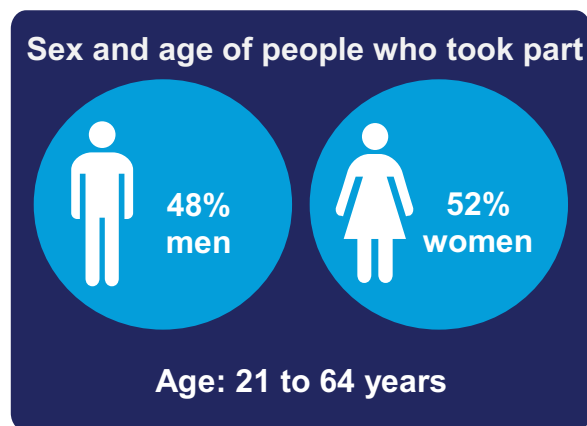
For this purpose, the study measured how much semaglutide from the two different tablets was found in the blood of people.

## Type of study

This was a 'phase 1' study. Phase 1 studies test a new medicine to see if it is safe and checks how the body affects the medicine. Researchers give the medicines to a small number of people.

## 2 Who took part in this study?

This study included 278 healthy men and women from Germany.



To be in the study, the men and women had to:

- be considered healthy by the doctor
- be between 18 and 64 years of age
- have a body mass index (BMI) between 20.0 and 29.9 kg/m<sup>2</sup>. BMI is a measure of a person's weight in relation to their height.

People could not take part in the study if:

- they had an HbA<sub>1c</sub> of 6.5% or greater. HbA<sub>1c</sub> is a blood test that measures the average blood sugar for the past 2 to 3 months.
- they were smoking more than 5 cigarettes per day at study start.
- they had any stomach disorders or surgeries.
- they themselves or their family member have or had cancer of the thyroid or other glands which produces hormones.
- have or had swelling in the pancreas.

## 3 Which medicines were studied?

There were 2 different types of semaglutide tablets used in the study. Both types of tablets had three different doses of semaglutide.

**Semaglutide tablets:** Tablets containing 3 mg, 7 mg and 14 mg semaglutide.

**Semaglutide C tablets:** New tablets containing 2.4 mg, 5.6 mg and 11.2 mg semaglutide.

There were 3 consecutive treatment periods – low, medium, and high dose. In each treatment period, people received either a semaglutide tablet or a semaglutide C tablet.

The dose of semaglutide was increased every 4 weeks:

- Low dose period (Day 1 – 28):  
2.4 mg or 3 mg once per day
- Medium dose period (Day 29 – 56):  
5.6 mg or 7 mg once per day
- High dose period (Day 57 – 84):  
11.2 mg or 14 mg once per day

People in the study were assigned to one of 6 treatment sequence based on the type of tablet they got by chance. All people in the study got both types of tablets.

People were not allowed to eat anything for 6 hours or drink anything for 2 hours, before taking the tablet. They could eat food or drink water 30 minutes after taking the tablet.

This was an open-label study. This means that both the researchers and the people in the study knew who was getting which medicine.

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## 4 What were the overall results of the study?

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The researchers found that:

- The amount of semaglutide in the blood was higher with the semaglutide C tablet at reduced doses than with the semaglutide tablet.
- The 3 mg, 7 mg and 14 mg doses in the semaglutide tablet should be reduced by 41% in the semaglutide C tablet to provide the same amount of semaglutide in blood.

More details on this study can be found on the websites listed in Section 10.

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## 5 What were the side effects?

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### What are side effects?

Side effects are unwanted medical 'events' which the doctor believes may be caused by the medicine in the study.

Some people in the study had side effects.

A side effect is serious if it:

- leads to death,
- is life-threatening,
- puts someone in the hospital or keeps them in the hospital for a long time,
- causes a birth defect,
- causes a disability that lasts a long time or
- needs medical or surgical treatment to prevent any of the above, as judged by the doctor.

### what were the serious side effects?

1 of 278 people (0.4% of all participants) who got the study medicine had a serious side effect of headache. This was observed in a person who was taking semaglutide tablet 14 mg.

No one died in this study.

### What were the most common side effects?

In the study, 188 of 278 people (68%) had side effects. These were seen most often when people were taking semaglutide C tablets.

- 141 out of 255 (55%) people had 547 side effects while taking semaglutide C tablets
- 126 out of 256 (49%) people had 445 side effects while taking semaglutide tablets

The most common side effects were:

Stomach and gut related problems (like feeling sick (nausea), being sick (vomiting), upset stomach (diarrhoea), indigestion (dyspepsia) stomach pain (abdominal pain) and release of gas from stomach (eructation)).

- 104 out of 255 (41%) people had these while taking semaglutide C tablets
- 88 out of 256 (34%) people these while taking semaglutide tablets

Problems related to food intake (e.g. low appetite):

- 55 out of 255 (22%) people had these while taking semaglutide C tablets
- 51 out of 256 (20%) people had these while taking semaglutide tablets

Headache:

- 41 out of 255 (16%) people had this while taking semaglutide C tablets
- 50 out of 256 (20%) people had this while taking semaglutide tablets.

Side effects were seen most often when people were taking semaglutide C tablets as compared to semaglutide tablets. Based on the type of side effects reported, the researchers think that this could be due to higher amount of semaglutide in the blood after taking the semaglutide C tablets.

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## 6 How has the study helped people and researchers?

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This study is just one of many studies. The studies are done to find out how best to use semaglutide to treat people with type 2 diabetes.

In this study, the amount of semaglutide found in the blood of people was higher when they got semaglutide C tablets as compared to semaglutide tablets.

They also found that the amount of semaglutide in the semaglutide C tablet can be further reduced to have semaglutide blood levels similar to the semaglutide tablet.

Findings from this study will be used to further:

- optimise the use of oral semaglutide.
- study the safety and efficacy of oral semaglutide in treatment of type 2 diabetes.

These results are for this study only. Other studies may show different results.

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## 7 Are there plans for further studies?

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Studies with semaglutide tablets are still going on. More studies are planned.

Details on these studies will be posted on the websites listed in Section 10.

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## 8 Study name

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**Study name:** A comparative bioavailability trial of steady state semaglutide exposure with the current formulation (semaglutide) and a new formulation (semaglutide C) of oral semaglutide in healthy subjects.

**Phase of clinical development:** Phase 1

**EudraCT number:** 2019-002010-40

**UTN number:** U1111-1233-0878

**National Clinical Trial number:** NCT04109508

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## 9 Who sponsored the study?

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

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## 10 Where can I find more information?

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You can find more information about the study or the medicine at these websites:

- Summary of results and study report [www.novonordisk-trials.com](http://www.novonordisk-trials.com), NN9924-4564.
- US government clinical trials website [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (for this study: [NCT04109508](https://clinicaltrials.gov/ct2/show/study/NCT04109508))

For general information about clinical studies please go to:

[www.novonordisk-trials.com](http://www.novonordisk-trials.com)