

Summary of the results of the clinical trial for laypersons

STEP 1: Research study investigating how well semaglutide works in people suffering from overweight or obesity

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 the 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 June 2018 to April 2020.

The study was carried out in 16 countries:

- European Union (EU): Belgium, Bulgaria, Denmark, Finland, France, Germany, Poland.
- Outside the EU: Argentina, Canada, India, Japan, Mexico, Russia, Taiwan, United Kingdom and the United States.

The study went as planned.

Why is this study important?

People who are overweight or living with obesity are more likely to get diseases like type 2 diabetes and high blood pressure. Losing weight has been shown to lower the risk of developing these types of diseases.

People who are overweight or living with obesity are most often treated with exercise and changes in diet. But this may not result in a weight loss for all people.

Semaglutide is a medicine that is used for treatment of people with type 2 diabetes. Studies show that semaglutide may also help people lose weight. In this study, researchers looked further into this.

What did researchers want to find out?

The researchers wanted to know the effect of semaglutide on people's weight.

To check this, they compared semaglutide with placebo for 68 weeks in people who are overweight or living with obesity.

Placebo is a dummy medicine that looks like the active medicine but has no effect on the body. Comparing with placebo helped the researchers evaluate the effect of semaglutide.

Type of study

This was a 'phase 3' study. A phase 3 study tests a new medicine for a long time (often ½ - 1½ years) on several hundred people with a specific condition or disease.

2 Who took part in this study?

In this study, 1961 people who were overweight or living with obesity took part.

Sex and age of people who took part

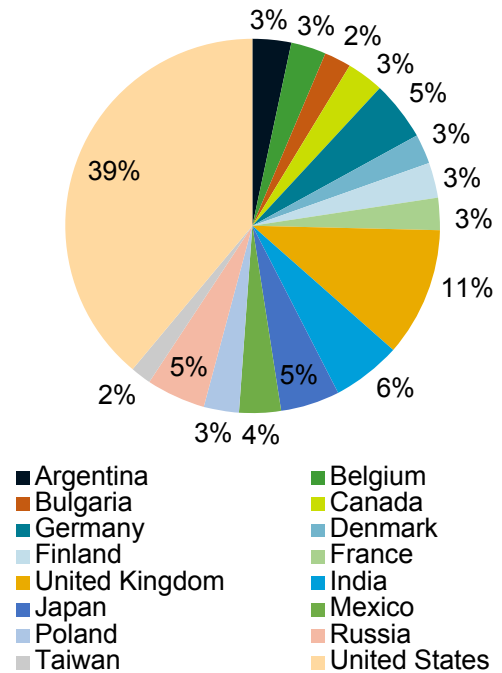


Age: 18 to 86 years

The study included:

- 430 people from the EU countries.
- 1531 people from the non-EU countries.

People who took part were from:



To be in the study, people had to:

- be 18 years of age or older.
- have body mass index (BMI) of
 - at least 30 kg/m² or
 - at least 27 kg/m² and have one or more of the weight related health problems: high blood pressure, increased amount of fat in the blood, sleep or heart related diseases.

BMI is a measure that uses a person's height and weight to work out if their weight is healthy.

- not been able to lose weight with diet alone.

People were not allowed to take part in the study if they had:

- diabetes.
- a change in body weight of more than 5 kg in the past 3 months.

3 Which medicines were studied?

The study compared semaglutide 2.4 mg with placebo.

Semaglutide 2.4 mg is a new medicine that may treat people who are overweight or living with obesity. It is similar to a hormone called GLP-1 (glucagon-like peptide-1) that the body makes. GLP-1 helps control the blood sugar and also affects the appetite.

Placebo is dummy medicine. It looks like the active medicine (semaglutide) but has no effect on the body.

For a fair comparison, people were divided into 2 groups at random by a computer:

- 1306 people got semaglutide 2.4 mg
- 655 people got placebo

People injected themselves with semaglutide or placebo under the skin once a week for 68 weeks.

The researchers and the people in the study did not know who got semaglutide and who got placebo. This is called a “double-blind study”. The researchers did this to make sure results were not influenced.

Researchers instructed people to be on a reduced calorie diet and to be more physically active throughout the study.

4 What were the overall results of the study?

After taking semaglutide or placebo for 68 weeks, people’s weight was compared to their weight when they joined the study.

The researchers found that people who got semaglutide 2.4 mg lost more weight than people who got placebo (see table).

More people who got semaglutide 2.4 mg lost at least 5% of their weight compared to people who got placebo (see table).

Doctors consider a weight loss of at least 5% important for improving health when being overweight or living with obesity.

	Semaglutide	Placebo
Weight loss	15%	2%
Percentage of people losing at least 5% weight	86%	32%

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

5 What were the side effects?

What are side effects?

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

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 longer time,
- causes a birth defect,
- causes a disability that lasts a long time or
- is an important medical event judged by the doctor to be serious for another reason than the above mentioned.

What were the serious side effects?

27 of 1306 people (2%) in the semaglutide 2.4 mg group and 4 of 655 people (0.6%) in the placebo group had serious side effects.

The most common serious side effects in the semaglutide 2.4 mg group were:

- Being sick (vomiting) and stomach infection (gastroenteritis).
Each happened in 4 of 1306 people (0.3%).
- Inflammation of the gallbladder (cholecystitis acute) and stones in the gallbladder (cholelithiasis).
Each happened in 2 of 1306 people (0.2%).

The serious side effects in the placebo group were:

- Gallstones (cholelithiasis)
- Parasitic infection (toxoplasmosis)
- Weight gain
- Allergy (hypersensitivity)

Each happened in 1 of 655 people (0.2%).

No one died of side effects during the study. Most people who had serious events had recovered at the end of the study

What were the most common side effects?

Stomach and gut problems were the most common side effects. Researchers expected this from earlier studies with semaglutide. Most of these side effects were mild and happened in the beginning of the study.

The most common side effects were:

Feeling sick (nausea):

- 550 of 1306 people (42%) in the semaglutide 2.4 mg group
- 100 of 655 people (15%) in the placebo group

Loose, watery and more frequent stools (diarrhoea):

- 359 of 1306 people (27%) in the semaglutide 2.4 mg group
- 82 of 655 people (13%) in the placebo group

Being sick (vomiting):

- 283 of 1306 people (22%) in the semaglutide 2.4 mg group
- 33 of 655 people (5%) in the placebo group

Difficulty in passing stool (constipation):

- 259 of 1306 people (20%) in the semaglutide 2.4 mg group
- 49 of 655 people (7%) in the placebo group

6 How has the study helped people and researchers?

In this study, researchers found that the people who got semaglutide 2.4 mg lost more weight compared to people who got placebo.

Findings from this study will be used to seek approval for using semaglutide to treat people who are overweight or living with obesity.

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

7 Are there plans for further studies?

Studies with semaglutide 2.4 mg are still going on. More studies are planned.

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

8 Study name

Study name: Effect and safety of semaglutide 2.4 mg once-weekly in subjects with overweight or obesity (STEP 1)

Phase of clinical development: Phase 3a

EudraCT number: 2017-003436-36

UTN number: U1111-1200-8053

National Clinical Trial number: NCT03548935

IND number: IND126360

Japanese registration number:

JapicCTI-183991

9 Who sponsored the study?

Research sponsor: Novo Nordisk A/S

Contact details of sponsor: Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd, Denmark

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10 Where can I find more information?

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

- Summary of results and study report
www.novonordisk-trials.com, NN9536-4373
- EU clinical trials register
www.clinicaltrialsregister.eu,
(for this study: 2017-003436-36)
- US government clinical trials website
www.clinicaltrials.gov,
(for this study: NCT03548935)
- Japan clinical trials website:
www.clinicaltrials.jp,
(for this study: JapicCTI-183991)

For general information about clinical studies please go to:

www.novonordisk-trials.com