

Summary of the results of the clinical trial for laypersons

Research study investigating how well semaglutide works in people living with overweight or obesity

About this summary

This summary gives the public information about a research study called a 'clinical study'. 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 December 2020 to August 2022.

The study was carried out in 3 countries:

- Region China (China mainland and Hong Kong)
- South Korea
- Brazil

The study went as planned.

Why is this study important?

Overweight and obesity is when your body stores too much fat compared to your height. People living with overweight or obesity are more likely to get high blood pressure and heart diseases. Losing body weight may lower the risk of developing these diseases.

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

Semaglutide is a medicine that is used for treatment of people with type 2 diabetes. Completed studies show that semaglutide may also help people both with and without type 2 diabetes to lose body weight. This was further assessed in this study.

What did researchers want to find out?

The researchers wanted to find out if semaglutide can help people living with overweight or obesity to lose body weight when used together with exercise and low-calorie diet.

To check this, they compared semaglutide with placebo for 44 weeks in people who are living with overweight or obesity. Some of the people in the study also had type 2 diabetes.

Placebo is a dummy medicine that looks like the active medicine but has no effect on the body.

Type of study

This was a 'phase 3' study. A phase 3 study tests a new medicine for a long time (often six months to a year-and-a-half) on several hundred people with a specific disease.

2 Who took part in this study?

In this study, 375 men and women living with overweight or obesity took part and were treated with semaglutide or placebo. Some of the people in this study also had type 2 diabetes (25.6%).

The study included:

- 300 people from Region China (China mainland and Hong Kong)
- 40 people from South Korea
- 35 people from Brazil



To be in the study, people had to:

- be 18 years of age or older.
- have at least 1 failed attempt of weight loss with change in diet.

People without type 2 diabetes also had to:

- have body mass index (BMI) of
 - at least 30 kg/m² or
 - at least 27 kg/m² with one or more weight related health problems such as 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.

People with type 2 diabetes also had to:

- have had type 2 diabetes for at least 180 days
- be treated for their diabetes with

- diet and exercise or
- up to 3 oral medicines for diabetes for at least 60 days either given alone or in combination with other drugs as per the local label.
- have BMI of at least 27 kg/m²

People who had lost or gained more than 5 kg weight in the past 90 days, could not take part in the study.

People without type 2 diabetes could not take part in the study, if they

- had a high level of glycated haemoglobin (HbA_{1c}) of more than 6.5% in their blood
- had previously been diagnosed with type 1 or type 2 diabetes.

People with type 2 diabetes could not take part in the study, if they:

- had poor kidney function.
- had eye problems related to diabetes.

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.

People were divided into 2 groups by chance (randomly) in a 2:1 ratio by a computer:

- 249 people got semaglutide 2.4 mg
- 126 people got placebo

People injected themselves with semaglutide or placebo under the skin (in the thigh, stomach or

upper arm) once a week for 44 weeks.

The study was a 'double-blind' study. This means that neither the people nor the doctors knew who got which study medicine. The researchers did this to make sure that the study results were not influenced in any way.

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 44 weeks, the researchers looked at the change in people's body weight since the time 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).

	Semaglutide	Placebo
Weight loss	12.1%	3.6%
Percentage of people losing at least 5% weight	85.3%	31.0%

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 thinks could 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
- needs medical or surgical treatment to prevent any of the above, as judged by the doctor.

What were the serious side effects?

The number of people with serious side effects were:

- 4 out of 249 people (1.6%) in the semaglutide 2.4 mg group
- 2 out of 126 people (1.6%) in the placebo group

In the semaglutide 2.4 mg group, the serious side effects were:

- Infection of the nose, sinuses or throat (upper respiratory tract infection) happened in 2 people (0.8%).
- Spread of tooth infection to internal spaces in the head and neck (facial infection), happened in 1 person (0.4%).
- Stomach infection (gastroenteritis) happened in 1 person (0.4%).
- Infection of the gums (periodontitis), happened in 1 person (0.4%).

In the placebo group, the serious side effects were:

- Stomach infection (gastroenteritis) happened in 1 person (0.8%).
- Miscarriage (abortion spontaneous) happened in 1 person (0.8%).

No one died in this study. Most people who had serious side effect had recovered at the end of the study.

What were the most common side effects?

Stomach and gut problems were among the most common side effects. These side effects were also seen in the previous studies with semaglutide. Most of the side effects were mild and happened in the beginning of the study and lasted for a short duration.

The most common side effects were:

Loose, watery and more frequent stools (Diarrhoea):

- 58 of 249 people (23.3%) in the semaglutide 2.4 mg group
- 10 of 126 people (7.9%) in the placebo group

Feeling sick (Nausea):

- 57 of 249 people (22.9%) in the semaglutide 2.4 mg group
- 8 of 126 people (6.3%) 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 body 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 on weight management in subjects with overweight or obesity (STEP 7)

Phase of clinical development: Phase 3a

EudraCT number: Not applicable

UTN number: U1111-1212-2189

National Clinical Trial number: NCT04251156

China drug trials: CTR20202040

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, NN9536-4379
- European Medicines Agency
www.ema.europa.eu <semaglutide (Wegovy)>
- US government clinical trials website
www.clinicaltrials.gov
(for this study: [NCT04251156](https://clinicaltrials.gov/ct2/show/study/NCT04251156))
- Chinese government clinical trials website
www.chinadrugtrials.org.cn

(for this study: [CTR20202040](#))

For general information about clinical studies
please go to:

www.novonordisk-trials.com