

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

# A research study to compare semaglutide with dulaglutide (both taken with metformin) in people with type 2 diabetes

### About this summary

This summary informs study participants and the public about a research study (called a 'clinical trial'). Results of research studies about medicines are described in a report. It is for researchers, health professionals and for people who approve medicines. This is a summary of that report.

Thank you to the participants and site 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 January 2016 to May 2017 in the following countries: Bulgaria, Croatia, Finland, Germany, Greece, Hong Kong, India, Ireland, Latvia, Lithuania, Portugal, Romania, Slovakia, Spain, United Kingdom and United States.

The study went as planned.

#### Why is this study important?

People with type 2 diabetes (T2D) have high levels of sugar in their blood. This is because their insulin does not work properly. Insulin is a hormone that helps control the amount of sugar in the blood. High blood sugar can be harmful to the body, and especially to the heart.

To treat T2D, medicines help the body lower blood sugar. There are many different treatments to help lower blood sugar.

This was a phase 3 study, meaning that it was done in a large group of people worldwide.

In this study, researchers compared the new treatment (semaglutide) with another once-weekly treatment in the same class (dulaglutide) used for T2D.

#### What did researchers want to know?

Researchers wanted to know more about semaglutide in treating people with T2D.

They wanted to compare how semaglutide and dulaglutide worked on blood sugar.

### 2 What people were included in this study?

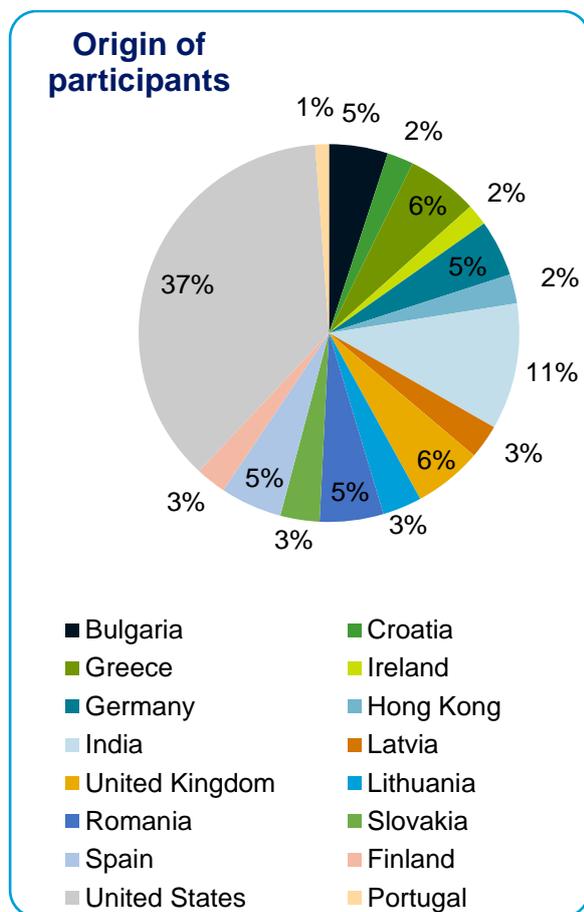
In this study, 1199 participants with T2D took part. All participants were taking metformin. Metformin is a medicine to help lower blood sugar. All participants had high sugar levels, and had their HbA<sub>1c</sub> measured. HbA<sub>1c</sub> is a measure of the blood sugar (levels) over the last 3 months.

People could not take part if they had

- an HbA<sub>1c</sub> below 7.0% or above 10.5%
- diabetic eye disease in need of urgent treatment
- a heart attack or stroke in the past 180 days
- other serious disease



598 participants from the European Union and 601 participants from Hong Kong, India and the United States took part.



### 3 Which medicines were studied?

#### About the study medicines

This study compared 2 medicines of a class of drugs called GLP-1-RAs. These medicines are a changed form of the human GLP-1 made in the body. GLP-1 is a hormone made in the gut. It helps the body release more insulin. Insulin helps to control blood sugar.

The study medicines were **semaglutide** and **dulaglutide**.

Semaglutide and dulaglutide are used in the US, and dulaglutide in Europe to help treat T2D.

The study medicines were taken by an injection pen. The medicine was injected with a needle under the skin.

Participants got study medicine once a week for 40 weeks.

#### About the study

The study participants were split into 4 groups by chance. 2 groups got semaglutide and 2 groups got dulaglutide. The participants and researchers knew what study medicine they got.

Each group got a different amount (dose) of study medicine.

- Group 1 got 0.5 mg of semaglutide.
- Group 2 got 0.75 mg of dulaglutide.
- Group 3 got 1.0 mg of semaglutide.
- Group 4 got 1.5 mg of dulaglutide.

Researchers compared groups 1 and 2 to each other. Researchers compared groups 3 and 4 to each other.

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

In this study researchers saw an improvement (lowering) in blood sugar levels with the majority of participants. The blood sugar levels were lower in participants who got semaglutide compared to dulaglutide, which was seen after 40 weeks with study medicine. Researchers looked at HbA<sub>1c</sub>. This is a blood test that shows how well blood sugar is being controlled. The mean HbA<sub>1c</sub> values at the end of the study are listed below

- Group 1: (0.5 mg of semaglutide) 6.72%
- Group 2: (0.75 mg of dulaglutide) 7.12%
- Group 3: (1.0 mg of semaglutide) 6.45%
- Group 4: (1.5 mg of dulaglutide) 6.86%

The participants in group 1 had lower HbA<sub>1c</sub> than in group 2. The participants in group 3 had lower HbA<sub>1c</sub> than in group 4.

These are the results from this study. Other studies may show something different.

## 5 What were the side effects?

### What are side effects?

Side effects are unwanted medical events thought by the doctor to be caused by the medicines in the study.

A side effect is serious if it:

- leads to death,
- is life-threatening,
- puts a participant in the hospital,
- keeps a participant at the hospital for a long time,
- causes a birth defect or
- causes a disability that lasts a long time.

Not all participants in this study had side effects.

### What serious side effects did the participants have?

6 of 601 participants (1%) had serious side effects after taking semaglutide.

Serious side effects were:

- Inflammation of the pancreas
- Crohn's disease
- slowed movement of food from stomach
- low blood sugar
- high amount of lipase in blood
- allergic reaction

Each of these happened in 1 of 601 (less than 1%) participants taking semaglutide.

3 of 598 participants (1%) had serious side effects after taking dulaglutide.

Serious side effects were:

- road traffic accident along with face injury caused by passing out from low blood sugar
- high amounts of calcium in blood
- stomach pain

Each of these happened in 1 of 598 (less than 1%) participants taking dulaglutide.

The participants taking semaglutide had a similar amount of serious side effects to those taking dulaglutide.

### What were the most common side effects?

The most common side effects that affected more than 1 of 10 participants were:

feeling sick in the stomach (nausea)

- 118 of 601 (19.6%) participants on semaglutide
- 89 of 598 (14.9%) participants on dulaglutide

loose stools (diarrhoea)

- 58 of 601 (9.7%) participants on semaglutide
- 55 of 598 (9.2%) participants on dulaglutide

Other common side effects were:

throwing up (vomiting)

- 55 of 601 (9%) participants on semaglutide
- 33 of 598 (6%) participants on dulaglutide

not feeling hungry

- 49 of 601 (8%) participants on semaglutide
- 38 of 598 (6%) participants on dulaglutide

high levels of lipase in blood

- 31 of 601 (5%) participants on semaglutide
- 26 of 598 (4%) participants on dulaglutide

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

This study is part of a programme that includes many final and planned studies. This is to find out how semaglutide should be used to treat people with T2D. This was only one study; other studies may show different results.

Findings from this study will be used to further improve the optimal use of semaglutide.

## 7 Are there plans for further studies?

Studies with semaglutide are still going on and more studies are planned.

Details on these studies can be found on the websites listed in Section 10.

For general information about clinical studies please go to:

[www.novonordisk-trials.com/website/content/about-clinical-trials.aspx](http://www.novonordisk-trials.com/website/content/about-clinical-trials.aspx)

## 8 Study name

**Study name:** Efficacy and safety of semaglutide versus dulaglutide as add-on to metformin in subjects with type 2 diabetes

**Phase of clinical development:** phase 3b

**EudraCT number:** 2014-005375-91

**UTN number:** U1111-1164-8495

**National Clinical Trial number:** NCT02648204

**IND number:** 79,754

## 9 Who sponsored the study?

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

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## 10 Where can I find more information about this study?

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

- Summary of results and study report  
[www.novonordisk-trials.com](http://www.novonordisk-trials.com)
- dulaglutide (Trulicity®)  
[www.ema.europa.eu](http://www.ema.europa.eu)
- EUs clinical trials register  
[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu), 2014-005375-91
- US government clinical trials website  
[www.clinicaltrials.gov](http://www.clinicaltrials.gov), NCT02648204