

STEP UP T2D

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Why are we doing this study

We are doing this study to look at how well a new investigational dose of semaglutide (7.2mg) works in lowering body weight in people with excess body weight. We will compare to a “dummy” medicine (placebo) and a lower dose of semaglutide (2.4mg).

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Deciding if you want to take part

- Have you tried **unsuccessfully** to lose weight?
- Does your **BMI** define you as obese?
- **Voluntary** participation
- **No fee** for taking part
- You can **stop** at any time

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What will you need to do if you take part?

- **Inject** the investigational study medicine **once a week** (in your stomach, thigh or upper arm)
 - When you reach the highest dose level you might need to take **3 consecutive injections** to get the planned dose. This is only for a short period of time until a new single dose pen for the highest dose is developed.
 - **Reduce the amount of calories in your diet**
 - **Increase your physical activity**
 - **Attend** all study visits
 - **Keep in contact** with the study staff during your participation in the study
- If you would like to take part in the study please sign the **Informed Consent Form**.

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What might be the benefits to you?

- **Free intensive lifestyle counselling**
- **Free regular tests, checks and talks** with your study staff
- **Help other people** suffering from overweight and obesity

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What are the possible side effects or harms of taking part?

- **Your study doctor will monitor you closely**
- Most common side effects from semaglutide are; **nausea, vomiting, diarrhea, constipation, low appetite, pain in your stomach area**
- The stomach and gut problems are usually **mild to moderate** and **short-lived**
- **Always tell your study staff about any side effects or health problems you have while taking part**

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What do you need to know about the investigational study medicines?

You will receive either investigational semaglutide OR “dummy” medicine (placebo)

QUESTIONS?

STEP

semaglutide | treatment
effect in people with obesity

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What will happen at the visits?

There will be **16 clinic visits (1–2 hrs)** and **7 phone calls (15-30 min)**:

- **Food and physical activity counselling**
- **Electrocardiogram (ECG) to check your heart**
- **Blood samples**
- **Eye examinations**
- **Weight and waist circumference** measurements
- **Fasting** visit (except for water) at some visits
- **An interview and questionnaires** about your mental health and good habits/cravings.
- Women of childbearing age will have a **pregnancy test** at each visits

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Pregnancy

Do not take part in this study if you are pregnant, breastfeeding or planning to get pregnant

- Women who can become pregnant should use highly effective birth control throughout the **entire study** period and at least **9 weeks** after last dose
- If you think you might be pregnant, take a pregnancy test and tell the study staff straight away
- If you become pregnant, stop taking the study medicine immediately
- Information on you, your pregnancy and your baby will need to be collected

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Who is involved?

- **Novo Nordisk** study
- Approved by an **ethics committee**

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Data protection

- Your information will be stored in a database
- All information/samples will be anonymous
- Novo Nordisk will protect your identity at all times

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Who can you talk to for more information?

Contact study staff for more information