



# Taking part in the ONWARDS 4 clinical study

If you have type 2 diabetes, you might be interested in a new clinical study. This study, ONWARDS 4, will assess the effect and safety of an investigational, insulin icodec, for adults with type 2 diabetes.

Participants are currently needed for the ONWARDS 4 clinical study. This leaflet will provide you with an overview of what it means to take part in ONWARDS 4.



## ONWARDS 4

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## What is a clinical study?



Clinical studies are scientific investigations with human participants, which look at promising medications, treatments and devices to see if they are **effective and safe**.

They are carefully designed to answer specific scientific questions, and to improve the prevention, diagnosis and treatment of health conditions, such as diabetes.

### What happens in a clinical study?

The process of a clinical study is varied, and depends on the type of research question and the intervention being tested.

The study staff will explain to you what is involved before you agree to participate in a study.

In most clinical studies, participants will need to have additional clinic visits and tests compared with those needed for your normal diabetes management. Sometimes the study staff may need to call you between clinic visits.

### Why participate in a clinical study?

Choosing to participate in a clinical study is an important decision. By participating, you will contribute to the understanding of type 2 diabetes and different ways to treat this condition. Your study staff will support you and ensure you are fully informed about the study.



Millions of people take part in clinical studies every year. By choosing to participate in a clinical study, you can make a difference to your life and the lives of other people.

## What is the ONWARDS 4 clinical study?



**ONWARDS** is a global programme of clinical studies to investigate how well an investigational insulin taken once weekly, insulin icodec, controls blood sugar in people with diabetes. **Once-weekly** insulin icodec will be compared with insulins taken **once daily**, which are already available on the market.

All studies in the ONWARDS programme are sponsored by the pharmaceutical company Novo Nordisk A/S.

The ONWARDS 4 clinical study will involve approximately:



**~580 participants**



**~9 countries worldwide**



**8 months of study participation**

The purpose of **ONWARDS 4** is to investigate the **effect and safety of once-weekly insulin icodec** as an investigational antidiabetic treatment **versus once-daily insulin glargine, both in combination with insulin aspart**.

Novo Nordisk is doing this study to assess the effect of insulin icodec on:

- Blood sugar control
- Episodes of low blood sugar (hypoglycaemia)
- Total insulin dose
- Body weight
- Safety and side effects



## Who can take part in ONWARDS 4?

There are some key criteria that potential participants in the ONWARDS 4 study must meet. The study doctor will decide with you whether you meet these criteria, and if it is appropriate for you to participate.

### Key criteria

Adult men and women who:

- Have been diagnosed with type 2 diabetes for over 6 months
- Have been taking a once-daily basal insulin for over 3 months
- Have been taking a mealtime insulin 2 to 4 times a day for over 3 months.



## What will be required if I take part?

Initially, you will go through a screening process to ensure that you meet the study criteria. If you do, your study doctor will explain exactly what is expected of a study participant so you can make an informed decision.

Participation in ONWARDS 4 will include:

- Taking the study medication prescribed by your study doctor
- Using a medical device to measure your blood sugar levels
- Recording changes in your medication, blood sugar levels and well-being in an electronic diary that will be provided to you
- Attending regular clinic visits and answering phone calls for health checks over the 8-month study period.

### What are the benefits of participating?



Active participation in your own healthcare



Access to blood sugar testing equipment during the period of the study, and access to an investigational treatment before it is widely available



Receive regular medical care with expert clinicians



Help others by participating in medical research

### What are the risks of participating?



Some side effects that you may experience while using insulin include:

- Low blood sugar (hypoglycaemia)
- Your immune system may make antibodies to your medication, which may result in an allergic reaction
- Skin changes around the injection site



Participating in a study may take up more time and attention than standard treatment and care



## How will I measure my blood sugar during the study?

As part of the study, you will be provided with:

### Blood sugar meter and electronic diary (eDiary)

Your blood sugar meter measures the amount of sugar in your blood, and will send this information to your electronic diary (eDiary) via Bluetooth.

Your study staff will read your blood sugar levels and will decide what insulin dose you need next.

Your study doctor will then send you the next insulin dose and you will let them know when you have injected the next dose via your eDiary.



### Continuous blood sugar monitoring

The continuous blood sugar monitoring sensor sits under the skin of your stomach and measures the amount of sugar in your blood every 5 minutes. A transmitter sends the reading via Bluetooth to a blinded receiver (which stores your blood sugar levels but does not display them).

Your study staff will collect and store the receiver data at clinic visits and use it for research purposes.

# Participant clinic visit overview

 Clinic visits

 Telephone appointment

Clinic visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	Follow-up 1	Follow-up 2
Week number		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	28	31

## Before your clinic visit, remember:

 Attend clinic visit fasting*		✓										✓								✓								✓		
 Your finger-prick blood test		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

## What will happen at my clinic visit?

 Questions about your health and well-being	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
 Physical examination	✓																											✓			
 Eye examination	✓																											✓			
 Blood pressure and pulse	✓															✓												✓			
 Blood samples	✓	✓		✓				✓				✓								✓								✓		✓	
 Urine pregnancy test		✓																										✓		✓	
 ECG	✓																											✓			
 Body measurements	✓	✓														✓												✓			
 Continuous blood sugar monitoring		✓	✓	✓	✓	✓																			✓	✓	✓	✓	✓	✓	✓
 Receive study medication		✓						✓								✓									✓						
 Receive pen and blood sugar monitoring training		✓	✓					✓								✓									✓						

\*This means you cannot eat or drink, except for water, for 8 hours before the clinic visit. Your study staff will try to schedule these visits early in the day. ECG, electrocardiogram

# Insulin treatment



## How does insulin treatment work?

In some people with type 2 diabetes, the pancreas stops making insulin or the body becomes resistant to insulin. These changes affect the way the body processes sugar. Insulin treatment helps your body absorb sugar. You may need adjustments to increase your insulin treatment to make sure that your blood sugar levels remain well controlled.



## What are long-acting insulins?

Long-acting insulin works to keep your blood sugar levels steady throughout the entire day and night by increasing the sugar taken up by cells – including between meals and when you sleep.



## What are mealtime insulins?

Mealtime insulins act faster and for a shorter time in the body than long-acting insulins. They are effective at controlling blood sugar levels after consuming food and drink in people with type 2 diabetes.

# Your study medication



ONWARDS 4 is a randomised, controlled study. This means that the study medication you receive is decided by chance – like flipping a coin.

You will receive either:

- Once-weekly insulin icodec and mealtime insulin aspart 2 to 4 times a day, or
- Once-daily insulin glargine and mealtime insulin aspart 2 to 4 times a day.

The chance of receiving either study medication is the same.



## What is an open-label study?

ONWARDS 4 is an open-label study. This means that both you and study staff will know from the start of the study which of the study medications you have been assigned to receive.



## What is insulin icodec?

Insulin icodec is an investigational long-acting insulin developed by Novo Nordisk, which is designed to act for a longer time within the body versus existing insulins. It is administered using a pen once a week via injection under the skin (subcutaneous injection).

Based on early studies,<sup>1-3</sup> it is expected that once-weekly insulin icodec will provide similar control of blood sugar in people with diabetes to other once-daily long-acting insulins, with fewer injections.



## What is insulin glargine?

Insulin glargine is a long-acting insulin, which is used to treat type 2 diabetes. It is known to be effective at controlling blood sugar levels.

In this study, insulin glargine U100 is administered once a day via injection under the skin.



## What is insulin aspart?

Insulin aspart is a mealtime insulin, which is also used in the treatment of type 2 diabetes. It is effective at controlling blood sugar levels after consuming food and drink.

During the study, insulin aspart is administered 2 to 4 times a day at mealtimes, via injection under the skin. Your study doctor will tell you how often to inject insulin aspart.

1. ClinicalTrials.gov. Identifier: NCT03922750, A Research Study in People With Type 2 Diabetes to Compare Two Types of Insulin: Insulin 287 and Insulin Glargine. Available at: <https://clinicaltrials.gov/ct2/show/NCT03922750>; 2. ClinicalTrials.gov. Identifier: NCT03751657, A Research Study to Compare Insulin 287 Once a Week to Insulin Glargine (100 Units/mL) Once a Day in People With Type 2 Diabetes. Available at: <https://clinicaltrials.gov/ct2/show/NCT03751657>; 3. ClinicalTrials.gov. Identifier: NCT03951805, A Research Study to Compare Two Types of Insulin: Insulin 287 and Insulin Glargine in People With Type 2 Diabetes Who Have Not Used Insulin Before. Available at: <https://clinicaltrials.gov/ct2/show/NCT03951805>



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