NN9828-4150

A clinical research trial for people who have been newly diagnosed with type 1 diabetes

Have you or a family member been diagnosed with type 1 diabetes mellitus (T1DM) within the past 2-3 months? If so, you may qualify for a clinical trial that is currently underway with an investigational drug combination.

If you or your family would like more information, or would like to talk to someone about participating in this trial, please see the trial team contact information on the bottom of this information sheet.

What is **NN9828-4150**?

NN9828-4150 is the name of a clinical research trial for type 1 diabetes mellitus (T1DM) currently being conducted. T1DM is a disorder that arises when a person's immune system destroys its own insulin-producing cells. The lack of insulin results in a loss of blood glucose control. Standard care involves insulin injection and blood glucose monitoring. In the long term, a lack of blood glucose control and insulin production can result in diabetic complications.

The aim of the **NN9828-4150** trial is to investigate if a combination of 2 investigational drugs, in addition to the standard treatment prescribed by your doctor, is able to preserve the function of insulin-producing cells in the pancreas. The trial involves 2 investigational drugs: 1 is a daily injection and the other is an intravenous (IV) injection (every 6 weeks). The trial also involves regular visits to your doctor for approximately 1 ½ years.

Can I be involved?

There are some key criteria that you will need to meet to join the **NN9828-4150** trial. The trial doctor will assess if you meet the key criteria and whether or not you qualify for the trial. The trial doctor will be able to explain in more detail whether you are a good candidate to participate in the trial.

Key Criteria

You may qualify for the **NN9828-4150** trial if you:

- Have been diagnosed with type 1 diabetes mellitus in the past 2-3 months
- Are between 18-45 years of age
- Are available to attend visits at the physician's office every 2-4 weeks for up to 1 ½ years

What's involved in participating?

Before any trial procedures are performed, you will be asked to read and sign an Informed Consent Form (ICF). This is an important document. Before you sign it, you will be informed about all aspects of the trial, including your responsibilities as a participant, and all of your questions about participation in the trial will be answered. The information in this brochure is explained more fully in the ICF.

If you meet the key criteria, and are interested in taking part in the trial, the trial team will review your medical history and assess whether or not you meet the trial entry criteria. During participation in this trial you will continue to take your insulin treatment and any other medication you have been prescribed. If you qualify, you will be assigned to 1 of 4 trial groups, each involving a combination of 2 investigational drugs; 3 trial groups include placebo (a placebo is identical to the investigational drug but does not contain any active ingredient). A computer program will assign you randomly (like flipping a coin) into 1 of 4 trial groups. The group you are in will not be known by you, your doctor, or the trial team.

The trial will involve injections of 2 investigational drugs (or placebos), 1 as daily injections at home and the other as intravenous infusions (IV) every 6 weeks at the clinic. Your participation in the trial will last 1 ½ years and during this period you will attend several trial visits to the clinic.

What is a clinical trial?

A clinical trial is a research trial involving participants that is performed to determine whether a new investigational drug or medical device is safe and effective. Sometimes clinical trials are used to study different ways of using investigational drugs so they will be more effective, easier to use, and/or associated with decreased side effects. Clinical trials may also be performed to discover how to best use an investigational drug in a specific group of people. Very strict procedures are followed to protect the safety of trial participants. These procedures are reviewed by an ethics committee, and by the government's health authority.

Why participate in a clinical trial?

Choosing to participate in a clinical trial is an important decision. By participating, you will be contributing to the understanding of a medical condition, and different ways to treat the condition. You will also play an active role in your healthcare, which may make you feel more in control in the management of your T1DM. The potential benefits to you include possible improvement of your condition and relief of symptoms. However, the benefits are by no means assured as the safety and effectiveness of the investigational drug is still being studied. The trial team can help explain these to you so that you may be fully informed about whether you would like to participate.

During the trial you will need to come to the clinic for trial procedures every 2-4 weeks. Please see below the trial procedures for the first month of trial participation.

Screening/first investigational drug dosing day procedures:

VISITS/ ASSESSMENTS	VISIT 1 (Screening visit)	VISIT 2	VISIT 3 (First investigational drug dosing day)
Informed consent & eligibility	✓		
Demographics & medical history	✓	✓	
Vital signs & weight	✓	✓	✓
Physical exam & electrocardiogram (ECG)	✓		✓
Body temperature and respiratory rate	✓		✓
Investigational drug dosing			✓
Meal test		✓	
Blood test	✓	✓	✓
Urine test	✓		✓
Pregnancy test	✓		
Questionnaires			✓
Eye exam			✓

What do I do next?

The **NN9828-4150** trial is currently looking for trial participants. If you are interested in learning more, or if you or someone you know might want to be considered as a participant for this trial, please contact the **NN9828-4150** trial personnel at the Alberta Diabetes Institute Clinical Research Unit:

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