IRB Approved at the
Protocol Level
Nov 25, 2020

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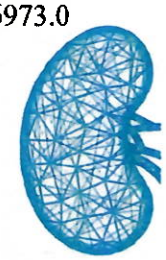

What is the REMODEL study?

REMODEL is a clinical study, which will include 105 people with type 2 diabetes and chronic kidney disease from 7 countries worldwide and will run for approximately 2 years.

REMODEL is a clinical study exploring how the medicine 'semaglutide' may help fight chronic kidney disease in people with type 2 diabetes.

Many clinical studies have already been conducted with semaglutide. A previous study has shown that using semaglutide may reduce the progression of kidney disease and the risk of cardiovascular events in some people with type 2 diabetes. Semaglutide is already approved in many countries, including the US, European Union and Japan, and can be prescribed by doctors to treat type 2 diabetes.

What are the benefits of taking part in REMODEL?

There are several benefits of taking part in REMODEL. For example, you can:

- Take a more active role in your own healthcare
- Get frequent medical care from experts at leading healthcare facilities to ensure that your diabetes is well-controlled during the study
- Have additional talks with study staff to discuss healthy lifestyle choices
- Help others with type 2 diabetes and chronic kidney disease in the future by contributing to medical research

What are the potential drawbacks?

There may be some potential drawbacks to taking part in REMODEL:

- You may experience side effects.
  The most common side effects of semaglutide are gastrointestinal problems such as nausea, diarrhoea and vomiting
- Your study medicine may prove to be ineffective against kidney problems
- The study may require more of your time and attention than normal treatment, and may include extra clinic visits and examinations

You should tell your study doctor or the study staff about any side effects or health problems you have while taking part in the study, even if you do not think they are caused by the medicine.

Before taking part in REMODEL, the study doctor or study staff will provide both verbal and written information about the study, including possible benefits and drawbacks of participation in the REMODEL study. This is to allow you to make an informed choice.

How is my personal data handled?

The information collected from you during the study is made anonymous and entered into a database together with information from everyone else in the study. This is then analysed by doctors and scientists. Your information is protected and treated with confidentiality.

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Who can join REMODEL?

To join the study, you must:

- Be over the age of 18
- Have type 2 diabetes and chronic kidney disease
- Be able and motivated to attend 11 clinic visits and 2 phone contacts throughout roughly a 1-year study period.

This study includes magnetic resonance imaging (MRI) scans of your kidneys, which is a test that shows a detailed picture of organs and other parts inside the body. The MRI scanner uses a magnetic field that affects metallic objects, and you can therefore not take part in the study if you have metal implants of certain types (e.g. pacemaker and cochlear implant) or permanent makeup/tattoos that your study doctor thinks could be a risk for you.

Some participants in this study will also have kidney biopsies taken. If you have agreed to have kidney biopsies taken in this study, please read the 'What Are Kidney Biopsies' brochure for more information on the procedure.

What will be required if I take part?

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

- A once-weekly injection of the study medicine or placebo, prescribed by the study doctor
- Attending regular study visits for study-related health checks
- Regular contact with the study staff or doctor throughout the study

Will I get paid?

You may receive payment for taking part in the study. You may be reimbursed for travel expenses, meals and inconveniences related to your participation in this trial. Please speak to the study staff about reimbursement.

Will I know which study medicine I am receiving?

You will not know which medicine you have, and neither will your study doctor or the study staff.

REMODEL is a 'placebo-controlled' study, which means that you will be randomly assigned to receive either the real medicine 'semaglutide' or a 'dummy' medicine called placebo. The medicine will be given in addition to your regular diabetes medication.

Which of the two medicines you will get is decided by chance. At the end of the study, you will be told which medicine you were given. You will also have an opportunity to see the results of the study.

Will my diabetes be adequately controlled for the duration of the study, even if I am taking the placebo?

Regardless of which trial medication you receive (semaglutide or placebo), your study doctor will ensure that you are treated according to the best standard of care. Your diabetes treatment will be reviewed continuously and will, if necessary, be adjusted so that your diabetes is well-regulated throughout the study period.

Do I need to attend every study visit?

For the study to succeed, it is vitally important that you attend as many study visits as possible. Attending regular study visits helps us understand the effect of the medicine, and it gives you the opportunity to discuss any health-related questions or concerns with your study doctor.

You will be able to discuss the visits with your study doctor and organize timeslots that work best with your schedule.