

Who can take part?

You, or someone you care for, may be able to take part if you/they:

- are 30–80 years of age
- have been diagnosed with T2DM and CKD
- do not require kidney dialysis.



What else do I need to consider?

- The study team will explain the possible benefits and risks of the study.
- You do not have to take part in the study if you don't want to.
- If you choose to take part in the study, you can stop participating at any time.
- You may be paid to take part in this study and you may be reimbursed for study-related travel costs.
- All study treatments and study-related tests will be provided at no cost to you.
- A team of doctors and nurses will monitor your health carefully during the study.

How do I get more information?

To find out more about the *proact* study, contact the study team using the information provided here. Study participation is voluntary. By contacting us, you are under no obligation to take part in the study.

Contact Us:
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Patient Information

A new generation of treatment
may be within you.

What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about an investigational product or therapy, such as:

- Does it work?
- How safe is it?
- Are there side effects?

All medications and medical therapies must be tested in clinical research studies before they can be approved to prescribe to patients. Without people taking part in these studies, we would have no new medications or medical therapies.

Deciding to take part in a clinical research study is your decision. If you have any questions, you can contact the study team using the information provided in this brochure.

About the *proact* study

The *proact* study is looking at an investigational product for people with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD), called Renal Autologous Cell Therapy (REACT). The investigational product is made using a person's own kidney cells from tissue collected by kidney biopsy.

The study will see if the investigational product is safe and whether it works to improve function in kidneys damaged by T2DM.

What will the *proact* study involve?

If you take part, you will be in the *proact* study for up to 5 years. You will:

- visit the study center at least 13 times in the first 6 months of the study (this may include 2 overnight stays)
- have 1 telephone follow-up visit
- have follow-up visits at the study center every 3 months until the study ends.

You will be assigned to 1 of 2 study groups by chance (like flipping a coin). One study group will undergo a biopsy and receive 2 injections of the investigational product. The other study group will undergo a simulated (fake) biopsy, (no tissue will be collected) and receive 2 simulated (fake) injection procedures (nothing will be injected into or around the kidney).

The study is made up of 7 parts:

