FREEDOM-1

Clinical study for kidney transplant recipients.

Tolerance induction after living donor kidney transplant.

If you qualified to receive a kidney transplant from a living donor, you and your living donor may be eligible to participate in a research study called **The FREEDOM-1 Study.** This brochure provides you with an overview of the study and important information for donors and recipients. Talk to your doctor to get more detailed information.

What is the FREEDOM-1 Study?

The FREEDOM-1 Study is a research study of an investigational cell therapy called FCR001 to prevent rejection of a transplanted kidney from a living donor. This study is supported by positive results from a pilot study in living donor kidney recipients. FREEDOM-1 will compare the efficacy and safety of FCR001 treatment to standard anti-rejection treatment.

What is FCR001 Cell Therapy and how does it differ from standard anti-rejection treatment?

Currently, kidney transplant recipients must take life-long anti-rejection drugs to prevent rejection of the kidney. These drugs are associated with serious side effects, including damage to the transplanted kidney over time.

FCR001 cell therapy is comprised of processed living stem cells obtained from the kidney recipient's living kidney donor. When infused in a recipient who is properly conditioned to accept the stem cells, tolerance of the transplanted kidney may be induced allowing withdrawal of anti-rejection drugs.

What is the purpose of this study?

The purpose of this study is to learn more about the safety and effectiveness of FCR001 treatment to prevent rejection of living donor kidney transplants without the need of life-long anti-rejection drugs.

How does this study work?

Qualifying recipients and their living donors will be randomly assigned as a pair to either FCR001 cell therapy (FCR001 group) or standard anti-rejection treatment (Control group). Twice as many recipients will be assigned to receive FCR001 cell therapy compared to standard treatment, thus 2 out of 3 donor/recipient pairs will be assigned to the FCR001 group.

Continued on page 2

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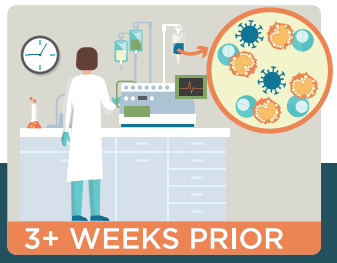
Mobilization/Apheresis

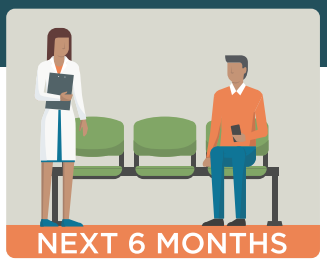


FCR001 Manufacturing

Recipient Conditioning

Transplant

FCR001 Infusion



Receive standard anti-rejection drugs; follow-up visits

Remove/lower dose of anti-rejection drugs if donated stem cells have engrafted in the recipient.

Free of Anti-rejection Drugs

How does this study work? — continued

FCR001 group kidney recipients will also undergo mobilization and apheresis. The stem cells collected will be stored at the study center in case the recipient needs them after the transplant.

FCR001 group kidney recipients will receive "conditioning" with several drugs and radiation starting 4 days before the kidney transplant surgery. The "conditioning" allows acceptance of their donor's stem cells contained in the FCR001 cell therapy. FCR001 will be infused intravenously into conditioned recipients about 24 hours after transplant surgery.

FCR001 group kidney donors will donate immune stem cells 3-8 weeks before kidney donation. This involves taking "mobilization" drugs for 5 days that stimulate stem cells to enter the blood from the bone marrow followed by collection of the stem cells by "apheresis" (similar to a blood donation).

FCR001 group kidney recipients will take standard anti-rejection drugs for the first 6 months, then taper the doses and stop after Month 12.

This is an investigational study. FCR001 is not yet approved by the US FDA and you should consult your doctor about whether you might be a good candidate for this study.

Control group kidney recipients will not undergo mobilization, apheresis or conditioning prior to their transplantation surgery. They will receive treatment with standard anti-rejection drugs.

FCR001 and control group kidney recipients will have regular study visits over the entire 5-year study.

FCR001 group kidney donors will be followed for 1 year.

Control group kidney donors will leave the study after transplant surgery.

Will I be compensated for my participation?

It will not cost the donor or the recipient anything to participate in the study. All reasonable travel and accommodations costs for both the donor and the transplant recipient will be covered for all study visits, regardless of whether they are randomized to the control arm or to receive FCR001. Moreover, the sponsor will cover the cost of all anti-rejection drugs for all study participants (if needed) for up to five years post-transplant.

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