

Investigational Celution® Prepared ADRC



The investigational Celution® prepared ADRCs in the ACT-OA clinical trial are autologous, which means a patient's own cells and not someone else's are injected into your knee.



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Once you have agreed to participate in the ACT-OA clinical trial and have been deemed eligible by the study doctor, a time will be scheduled for you to have the procedure. The procedure consists of 3 phases: 1) liposuction to collect adipose (fat) tissue from your body, 2) preparation of your ADRCs, and then, 3) injection of your ADRCs (or placebo) into one of your knees.

The Study Procedure:

- 1. At the start of the procedure, all trial participants (including those who will receive placebo) will undergo a fat collection (liposuction) procedure to remove approximately 1½ cups of their adipose (fat) tissue. This procedure will be conducted under local anesthesia with or without medications to make you sleepy. This will be determined by your study doctor in discussion with you.
- 2. The fat tissue collected from you will then be processed using the investigational Celution® device to prepare ADRCs. During the ADRC preparation time (approximately 3 hours) you will be resting.
- 3. After preparation of your ADRCs is complete, the appropriate study treatment (your ADRCs or placebo) will be injected into one of your knees with a small needle.
 - First, you will receive local anesthetic around the injection area and any excess fluid that is in the knee joint will be removed. Then the study treatment will be injected.
 - Patients in the placebo group will receive an injection with an inactive placebo, visually the same as ADRCs. You will have a 67% chance of receiving ADRCs and a 33% chance of receiving placebo. Remember, this is a double-blind study, so the study doctor, the study staff, and you will not know what investigational treatment you receive.

The entire procedure from the start of the liposuction through to completion of the knee injection will take approximately 5 hours and you will then be able to return home the same day. Follow-up visits occur at 1, 2, 4, 8, 12, 24 and 48 weeks after the procedure. In addition, the study doctor and study staff will always be available to you if you have questions or concerns.