What will happen if you join the study?

• At least two weeks before administration of the study treatment, you will be given a general or local anaesthetics to avoid any pain during the procedure. Your fistula(s) will be examined, the damaged tissue removed, the area cleaned and some surgical thread put in to encourage healing. You will also be given antibiotics for 7 days to prevent infection.

• On the day of the treatment procedure, the surgical thread will be removed and the stem cells or placebo carefully injected directly into the fistulas. An overnight stay in the hospital will not be required. Even if you are in the placebo group, you may still have benefitted from the removal of the damaged tissue and the use of the thread.

• Following the procedure, you will need to visit the clinic again six times over the course of one year so the study team can assess how you are doing using tests and questionnaires. They will also examine how well your fistulas are healing with repeat MRI scans at weeks 24 and 52.

• Between visits you will be asked to keep a daily 2-week diary recording your Crohn’s Disease symptoms, the number of pads you use and how painful it is when standing, sitting and having a bowel movement. We will give you a small electronic device to record this information digitally.

Please remember

Previous research has shown that the investigational treatment is promising and, by taking part in the ADMIRE-CDII Study, you will help doctors gain further understanding of its value in treating people with your condition. There is no guarantee that taking part in the study will benefit you personally but your safety and wellbeing will be a priority for the study team at all times. All tests and treatment related to the study will be provided at no cost to you or your insurers. You will not be paid for participating in the study but reasonable expenses related to study visits will be reimbursed.

Contact information

If you would like more information about the ADMIRE-CDII Study, please contact us using the details below. Contacting us does not mean you have to participate in the study.

Clinic name: UCI Stem Cell Research Center
Contact person: Dr. Nimisha Parekh
Address: 101 The City Drive S. Orange, CA 92868
Email: stemcell@uci.edu
Telephone: (949) 824-3990

The ADMIRE-CDII Study
Are Crohn’s related complications controlling your life?

What is a clinical research study?

Clinical research studies are designed to find out how effective and safe potential new treatments (investigational treatments) are when used in particular medical conditions. Depending on the results of the research studies, the treatment could later be made available for doctors to prescribe routinely. Without clinical research studies, medical progress could not be made – and almost every medicine you have ever taken will previously have been tested in clinical research studies as the one you are being proposed. Clinical research studies are performed according to strict regulations, guidelines and codes of practice which help ensure that the participants’ safety and rights are protected throughout the study. Even if you agree to join a clinical research study, you will still be free to withdraw from the study at any time and receive the usual recommended treatment for your condition if you wish.
### Why are new types of treatment needed for perianal fistulas?

People with Crohn’s Disease have inflammation in the bowel which can eventually damage the bowel lining. This is thought to be why nearly one in three people with Crohn’s Disease eventually develop perianal fistulas, where the damage from the inflammation leads to one or more openings (like small tunnels) between the end of the bowel and the skin near the anus. Perianal fistulas can be difficult to live with, very painful (especially when sitting down) and they usually do not heal on their own. Even with the latest medications, most perianal fistulas do not improve much - and if they do, they usually open up again once the medication is stopped. Often the best hope of successful treatment is some type of surgery. This may involve a hospital stay and there can be problems like infection, re-development of the fistulas and even some loss of bowel control. For these reasons, developing new treatment approaches for perianal fistulas is really important and these need to be assessed in clinical research studies. The ADMIRE-CDII Study will be looking at a potential new treatment involving the use of stem cells.

### How is the ADMIRE-CDII study designed?

Half of the participants in the ADMIRE-CDII Study will be assigned to receive the stem cell treatment and the other half will receive placebo (plain salt water containing no stem cells or other treatment), both locally along the fistula(s) by a trained surgeon. This is important because the researchers will only be able to tell how helpful the stem cell treatment is if they can compare its effects with the effects of the placebo. The assignment to the stem cell group or placebo group will be done at random (like flipping a coin) so everyone has the same chance of receiving the real treatment. Participants will be able to continue with any medication they are taking for their Crohn’s Disease throughout the study (except for steroid medications).

### Who can join the ADMIRE-CDII Study?

- To qualify for the ADMIRE-CDII Study, your Crohn’s Disease will need to be under control or only mildly active and you will need to have already tried at least one type of medication for your perianal fistulas which has not been effective enough or has stopped working.

- Before deciding whether to join the study you will meet with the team to go through the informed consent form, which gives you all the information you should need to make a decision. You will be free to ask as many questions as you like to ensure you understand everything.

- You will also need to attend one or more ‘screening’ visits where the study doctor will carry out tests to check whether the study is suitable for you. These will include a colonoscopy (examination of the inside of your bowel using a thin flexible tube with a camera at the end) unless you have had one in the last six months and meet some additional requirements, and also an MRI scan, which involves lying flat in an enclosed tube while the scanner takes detailed images of your fistula(s) to assess their type, number and location.