ATLAS-UC

Clinical Research Study

Information for people 16-75 years old who are diagnosed with

ULCERATIVE COLITIS.

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Ulcerative Colitis

More than 5 million people worldwide have ulcerative colitis (UC). It can cause pain, stomach cramps, bloody diarrhea, and rectal bleeding. There are treatments for UC, but no cure.

What are clinical studies?

A clinical research study tries to answer questions about how medicines work in the people who take them. Researchers run studies to test whether an investigational medication is safe and effective. These studies may help doctors find new ways to help prevent, detect, or treat health problems. Clinical research studies may also be referred to as research studies or clinical trials.

What is the purpose of the ATLAS-UC clinical study?

Researchers are testing an investigational medicine in people diagnosed with moderately to severely active UC. They are evaluating the safety of the investigational medicine and how well it may work compared to a placebo. A placebo looks like the investigational medicine but contains no active ingredients.

Can I take part in this study?

You may qualify to take part in this study if you are 16-75 years old and:

- You have had UC for at least 3 months and currently have moderately to severely active UC
- You have had at least **1** of the below:
  - Have not responded well or stopped responding to at least 1 UC treatment
  - Have not tolerated your dose of corticosteroids being reduced (such as prednisone, budesonide, or beclomethasone)
  - Have not been able to tolerate taking at least 1 UC treatment

There are additional requirements that determine if you may qualify to be in this study, which the study doctor will discuss with you.

About the investigational medicine

During the study, you will be assigned to get the investigational medicine or a placebo. This is called the investigational study drug. The study drug will be given 2 different ways:

- As an intravenous (IV) infusion into your vein; an IV pump will be used to deliver the investigational study drug over 30 minutes.
- As a subcutaneous injection (shot) just under the skin in your thigh, abdomen, or upper arm using an autoinjector device. You will be trained to give the injection to yourself. If you prefer, a family member or caregiver can be trained to give you the injections. Or you can have a member of the study team give you the injections at the study clinic.

Will I get the investigational medicine if I take part?

Participants will be put into different groups to receive different doses of the investigational medicine or a placebo. Participants, the study doctor, and the study team will not know which group each participant is placed in.

What will happen if I take part?

The ATLAS-UC study is made up of 2 different studies. If you qualify and agree to take part, you will be in one, but not both studies.

Study 1 (about 1 and a half years long):

Screening Period (up to 5 weeks long): You will visit the study site 1 or more times for medical tests to see if you may qualify to be in this study.

Induction Period (about 3 months long): You will visit the study site 5 times and receive the assigned investigational study drug at the study clinic by IV infusion 4 times.

Maintenance Period (about 9 months long): You will inject the assigned investigational study drug every 2 weeks for about up to 9 months. It is possible you will not finish the maintenance period. If your UC symptoms are not responding well to the study drug, you may opt to go into the *reinduction period.* You will receive the investigational medicine by IV infusion 4 times and visit the study site 5 times over about 3 months. Participants in the reinduction period will not receive a placebo.

Follow-up Period (about 3 months long): If you do not enter the extension period, you will enter the follow-up period and have about 3 study site visits. You will no longer be taking the investigational study drug.

Study 2 (a little more than a half year long):

Screening Period (up to 5 weeks long): You will visit the study site 1 or more times for medical tests to see if you may qualify to be in this study.

Induction Period (about 3 months long): You will visit the study site 5 times and receive the assigned investigational study drug at the study clinic by IV infusion 4 times. If your UC symptoms are not responding well to the study drug, you may opt to go into the *reinduction period* after you complete the induction period. During the reinduction period, you will receive the investigational medicine by IV infusion 4 times and visit the study site 5 times over about 3 months. Participants in the reinduction period will not receive a placebo.

Follow-up Period (about 3 months long): If you do not enter the extension period, you will enter the follow-up period and have about 3 study site visits. You will no longer be taking the investigational study drug.

What is the optional extension period?

If your UC responds well to the investigational study drug, you may have the option to join the extension period. During the extension period, you will receive the investigational medicine by injection for up to 3 years. No one will receive a placebo during the extension period. The study doctor will discuss this option with you. You may be able to take part in the extension period even if you went into the reinduction period.

What are some of the medical tests and exams I will have during this study?

- Discuss your health history, medications, and how you are feeling
- Physical exam
- Blood, urine, and stool samples
- ECG (electrocardiogram, which measures your heart function)
- Endoscopy with biopsy
- Answer questions about your health, fatigue levels, and how your UC may be affecting your daily activities
- Chest X-ray or CT scan

Is there a cost to take part?

The study drug and all study-related tests are provided at no cost. You may be reimbursed for study-related travel expenses.

For more information, including the possible risks and benefits of taking part in this study, please contact:

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