

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 medicine at the study clinic by IV infusion 4 times.

Reinduction Period (about 3 months):

If your Crohn’s disease symptoms are not responding well to the investigational study medicine, you may opt to go into the reinduction period after you complete the induction period. During the reinduction period, you will receive the investigational study 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, as you have completed all your scheduled treatment visits or stopped treatment early you will enter the follow-up period. This includes 2 phone visits and 1 study site visit over about 3 months. You will no longer be taking the investigational study medicine.

What is the optional Extension Period?

The extension period is optional. After finishing with Study 1 or Study 2, participants may qualify to take part in the extension period if your Crohn’s

disease responded well to the study treatment. During the extension period, you will receive the investigational study 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
	Vital signs (heart rate, temperature, blood pressure, and weight)
	Blood, urine, and stool samples
	ECG (electrocardiogram), which measures your heart function
	Ileocolonoscopy with biopsy
	Answer questions about your health, fatigue levels, and how your Crohn’s disease may be affecting your daily activities
	Chest X-ray or CT scan

ARES-CD
Clinical Research Study

Is there a cost to take part?

The investigational study medicine 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:

Information for people
16-75 years old who
are diagnosed with
**CROHN’S
DISEASE**



Crohn's Disease

Crohn's disease causes inflammation (swelling) and affects the digestive tract (intestines/colon). There are treatments for Crohn's disease, 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 ARES-CD clinical study?

Researchers are testing an investigational study medicine in people diagnosed with moderately to severely active Crohn's disease. They are evaluating the safety of the investigational study medicine and how well it may work compared to a placebo. A placebo looks like the investigational study medicine but contains no active ingredients. MK7240 is experimental. It has not been approved for use.

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 Crohn's disease for at least 3 months and currently have moderately to severely active Crohn's disease
- You have had at least **1** of the below:
 - Have not responded well or stopped responding to at least 1 Crohn's disease treatment
 - Have not tolerated your dose of corticosteroids being reduced
 - Have not been able to tolerate taking at least 1 Crohn's disease treatment

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

What is the investigational study medicine?

During the study, you will be assigned to get the investigational study medicine or a placebo. Investigational study medicine 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 medicine 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. You can also choose to have a member of the study team give you the injections at the study clinic.

- How you receive the study treatment, either by intravenous infusion or subcutaneous injection, will be dependent on what period of the trial you are in.

Will I get the investigational study medicine if I take part?

Participants will be put into different groups to receive different doses of the investigational study medicine or a placebo. A computer will decide which group you are placed in. You have an equal chance of being put into each group. Participants, the study doctor, and the study team will not know which group each participant is placed in. In case of an emergency, they can find out.

What will happen if I take part?

The ARES-CD 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. How long you will be in Study 1 or Study 2 will depend on your response to treatment.

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 medicine at the study clinic by IV infusion 4 times.

Maintenance Period (about 9 months long):

You will inject the assigned investigational study medicine every 2 weeks for about up to 9 months. It is possible you will not finish the maintenance period. If your Crohn's disease symptoms are not responding well to the investigational study medicine, you may opt to go into the reinduction period.

Reinduction Period (3 months): You will receive the investigational study 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. This includes 2 phone visits and 1 study site visit over about 3 months. You will no longer be taking the investigational study medicine.

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