

ARES-CD

Clinical Research Study

What is Crohn's disease?

Crohn's disease (CD) causes inflammation (swelling) and affects the digestive tract (intestines/colon). There are treatments for CD, but no cure.

Why is this study being conducted?

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

About the investigational study medicine

tulisokibart is being tested to see if it may control the inflammation (a painful reaction from the immune system) and fibrosis (a thickening or scarring of tissue) caused by CD and help resolve or improve its symptoms.

How is the study medicine given?

The study medicine is given 2 different ways:

- As an intravenous (IV) infusion into your vein; an IV pump is used to deliver the 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. Or you can have a member of the study team give you the injections at the study clinic.

How would I qualify for the study?

You may qualify to take part in this study if you are 16 to 80 years old and:

- You have had CD for at least 2 months and currently have moderately to severely active CD
- You meet at least **1** of the following criteria:
 - » Have not responded well or stopped responding to at least 1 CD treatment
 - » Have not tolerated your dose of corticosteroids being reduced
 - » Have not been able to tolerate taking at least 1 CD 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 will happen during the study?

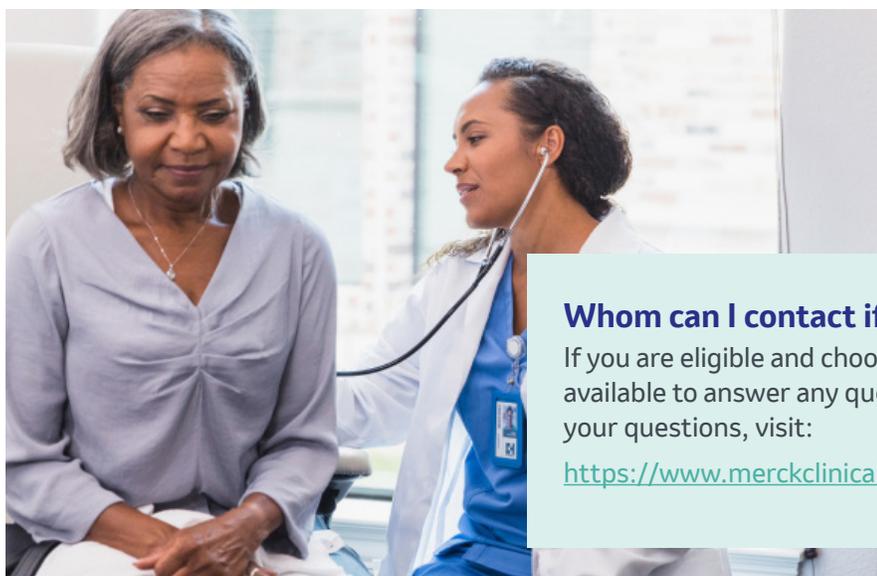
The ARES-CD study is made up of 2 different studies. If you qualify and agree to take part, you will be in 1, but not both studies.

How long will the study last?

The study will last about 6 to 18 months, depending on which study group you are in. There is also an optional extension period which will last approximately 3 years. During the extension period, all participants will get the investigational study medicine by injection.

What happens if I am eligible and decide to participate?

- You will receive the study medicine and all study-related medical tests at no cost
- Your CD and overall health will be closely monitored by a study doctor
- You may be reimbursed for study-related travel expenses
- You may help researchers learn more about CD and the investigational study medicine



Whom can I contact if I have questions?

If you are eligible and choose to participate, the study staff will be available to answer any questions you may have. For more answers to your questions, visit:

<https://www.merckclinicaltrials.com/faq/>