

Dr. Christopher Phillips
225 Medical Center Dr.
Suite 305
Paducah KY, 42003
270-441-4606

Dear Patient,

Four Rivers Clinical Research is taking part in a clinical research study called the contRAst-2 Study. This study is looking at how safe a potential new medication (investigational medication) is and whether it works for people with rheumatoid arthritis (RA).

We are looking for volunteers who are 18 years of age or older, have RA, and have swollen and painful joints despite taking one or more conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) for at least the past 12 weeks.

What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about an investigational medication. All medications must be tested in clinical research studies before they can be approved to prescribe to patients. Without people taking part in these studies, we would have no new medications.

About the contRAst-2 Study

RA is a chronic autoimmune disease that mainly affects the joints. In an autoimmune disease, the immune system (which normally protects the body from infections) works against itself and produces antibodies that attack certain tissues in the body. This results in inflammation, which in RA causes symptoms such as painful, swollen joints, stiffness, and fatigue.

A substantial proportion of patients with RA do not respond well to currently available RA therapies. Therefore, there is a medical need for more effective RA treatments that work in different ways.

The investigational medication in the study is a biological medication and has been developed to block a substance in your body called 'GM-CSF'. GM-CSF is thought to contribute to inflammation in our bodies and higher levels of GM-CSF are found in the joints of people with RA. It is hoped that blocking GM-CSF will reduce symptoms and slow progression of RA.

If you take part, you will be in the contRAst-2 Study for up to 1 year and 3 months. You will visit the study center at least 15 times for tests and assessments. You will receive study medication as a subcutaneous injection (injection under the skin) once a week at the study center and will take a capsule twice a day at home. You may be able to self-administer the study medication injections at home, if this option is available at your study center. During this study, you will continue to take one or two of the csDMARDs you are currently taking, as discussed with the study doctor

If you complete the treatment period, you may be able to take part in a long-term extension study where all participants will receive the investigational medication.

Are you interested in taking part?

You may be able to take part if you:

- are 18 years of age or older
- have been diagnosed with RA
- have swollen and painful joints despite taking one or more of the following csDMARDs for at least the past 12 weeks: methotrexate, hydroxychloroquine, chloroquine, sulfasalazine, leflunomide, bucillamine, or iguratimod.

All study medication, health assessments, and medical tests related to the contRAst2 Study will be provided to you at no cost. Your participation in this study will help us learn more about the investigational medication and RA. The results may help other patients with this condition in the future. For more information, please call me or a member of the study team.

By contacting us, you are under no obligation to take part in the study. You could also visit the patient website (www.contrastraprogram.com) to see if you may be eligible and to learn more about the study.

We look forward to hearing from you soon.

Sincerely

Dr. Christopher Phillips

Investigator

The contRAst-2 Study