

Scott & White Hospital & Clinics Clinical Research at Scott & White

Please complete this form for each of your studies that are currently enrolling subjects. This information will be used to create a web page available for viewing by the general public. Please use lay terminology as in the consent form. The information should be complete and accurately describe your studies.

Study Title: A Phase 2 Dose-Ranging Study of Multiple Subcutaneous Doses of LY2439821 (an Anti-IL-17 Antibody) in Patients with Active Rheumatoid Arthritis on Concomitant DMARD Therapy (Protocol #: 11F-MC-RHAK)

Project ID#: 90081

Department: Rheumatology

Sponsor: Eli Lilly

1. Provide a brief synopsis of the study (purpose of the study from abstract, consent form, or protocol using lay terminology):

Condition(s):	Treatment(s):
You have been diagnosed with active rheumatoid arthritis.	<ul style="list-style-type: none">• LY2439821 injection• LY2439821 placebo (control)

Rheumatoid arthritis (RA) is a type of autoimmune disease in which the body's own immune system attacks itself. RA primarily attacks the small joints in the hands, feet, and spine causing inflammation, pain, stiffness, and swelling inside the joint. If left untreated, RA can cause the joint to become deformed with limited or no movement. Currently, RA affects over 2 million people in the United States.

The purpose of this research study is to evaluate the effectiveness and safety of an investigational drug called LY2439821 for the treatment of subjects with RA. The study will also determine how much LY2439821 should be given to patients.

LY2439821 has not been approved for use by the FDA and is considered experimental.

2. Who is eligible to participate in the study (basic qualifications such as age, gender, etc.)?

Age: 18 - 75 years of age

Gender: Men and Women

- You have a current diagnosis of active RA.
- You are currently receiving a traditional DMARD (disease-modifying anti-rheumatic drug) such as methotrexate (MTX) and have been receiving this treatment for the last 8 weeks.
- You have never been treated with a biologic DMARD **OR** you have been treated with a biologic DMARD in the past and are no longer receiving treatment.

Patients **cannot** participate in this study if the following apply:

- You are currently pregnant or breastfeeding.
- You have a history of any mental condition that may affect your ability to participate in this study.

- You have tested positive for hepatitis B, hepatitis C, or HIV.
- You have taken a live vaccine (a drug that is made from a living organism) within the last 12 weeks.
- You have donated more than 300 mL (about 1 cup) of blood within the last month.
- You have participated in another clinical trial within the last 4 weeks.
- You have received LY2439821 in the past.

**** To be eligible to participate, you must meet other entry criteria required by the study protocol and the study doctor.**

3. What may be involved/required for subject participation (visits, tests, and/or logs, etc.)?

Study participation will last about 20-38 weeks consisting of at least 12 clinic visits.

There will be a screening period to determine if you are eligible to participate which may last up to 4 weeks. If you qualify, you will be randomly assigned (like the flip of a coin) to one of five doses of LY2439821 or placebo treatment. You will receive this treatment for 12 weeks.

A placebo is a pill or injection that looks like the study drug except that it contains no active medicine and provides no medical benefit. You will not know which treatment group you have been assigned to until your participation in the study is complete.

Office visits will take approximately 1 to 3 hours depending on the tests and procedures performed at that visit. Some of the tests and procedures that will be performed are listed below:

- Medical history including medications.
- Physical examinations including height, weight, and vital signs.
- Electrocardiograms (ECGs) - a test that measures the electrical activity of your heart.
- Routine blood/urine tests.
- Blood/urine pregnancy tests.
- Additional blood samples (serum, plasma, and RNA) will be collected for future testing.
- If you consent, an additional blood sample will be collected for optional genetic (DNA) testing.
- Health Assessment Questionnaire - Disability Index (HAQ-DI) - asks questions regarding how your RA affects your daily life.

Open-Label Extension Study

Subjects that complete the randomized treatment phase may choose to enter the open-label treatment phase in which all subjects will receive LY2439821 for a period of 48 weeks. Study participation will last about 56-68 weeks consisting of at least 15 clinic visits.

4. Contact Information:

Coordinator(s): Carla Brown

Title(s): Clinical Research Coordinator

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