

Locations

The following fifteen institutions are participating in the study:

Albert Einstein College of Medicine – Bronx, NY

Weill Cornell Medical Center – New York, NY

Ohio State University – Columbus, OH

University of Alabama at Birmingham – Birmingham, AL

University of California – Davis, CA

University of California – Los Angeles, CA

University of Cincinnati – Cincinnati, OH

University of Colorado Denver – Denver, OH

University of Kansas Medical Center – Kansas City, KS

University of Miami School of Medicine – Miami, FL

University of Pittsburgh – Pittsburgh, PA

University of Rochester – Rochester, NY

University of Texas Southwestern Medical Center – Dallas, TX

University of Virginia – Charlottesville, VA

Yale University – New Haven, CT

For More Information

Thank you for your interest in the Rituximab in Myasthenia Gravis clinical trial.

If you have any more questions, or are interested in being in this research study, please contact *Randev Sandhu* at rssandhu@ucdavis.edu and 916-734-4303.

Information can also be found on the NeuroNEXT website:

<http://www.neuronext.org>



A Phase II Trial of Rituximab in Myasthenia Gravis

UNIVERSITY OF CALIFORNIA
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Information for potential research participants with Myasthenia Gravis

A drooping eyelid, is the most frequent early sign of myasthenia gravis, a disease that produces extensive muscle weakness.



The study is coordinated by NeuroNEXT, the Network for Excellence in Neuroscience Clinical Trials, with support and funding from the National Institute of Neurological Disorders and Stroke (NINDS), a division of the National Institutes of Health (NIH).



National Institute of
Neurological Disorders
and Stroke



Frequent Questions about the study

What are common symptoms of MG?

Common symptoms include:

- A drooping eyelid
- Blurred or double vision
- Slurred speech
- Difficulty chewing and swallowing
- Weakness in the arms and legs
- Chronic muscle fatigue
- Difficulty breathing

There is no known cure for MG, and effective treatments allow many with MG to lead full lives.

What is the purpose of the study?

The study purpose is to learn if rituximab is a safe and effective drug for people with Myasthenia Gravis (MG) who are on prednisone. The study will determine if rituximab will help people take less prednisone to manage their myasthenia gravis or possibly be able to discontinue prednisone.

What is a placebo-controlled clinical trial?

A placebo-controlled clinical trial means there will be two groups of people being enrolled in this study. 25 people will receive the study medication (rituximab) and the other 25 people will receive a placebo (an inactive salt-water infusion).

What is Rituximab?

Rituximab is a type of medicine known as a monoclonal antibody (MAB). It works by reducing white blood cells called B cells.

How is Rituximab given?

Rituximab is given through a needle inserted into a vein; this is called an infusion.

What will happen if I choose to be in the study?

- Your first visit will include a review of the informed consent form. If you choose to be in the study, we will do various tests to make sure it is OK to include you in the study.
- You will get rituximab or placebo infusions weekly during the first four weeks of the study and during weeks 24 through 27 of your participation.
- You will come to regular study visits every 4 weeks. At these visits, you will have a MG focused physical examination and complete questionnaires. Blood samples will also be drawn at each visit.

What are some of the basic things necessary for me to be eligible to be in the study?

- You must be 21 to 90 years old
- You must have a diagnosis of generalized MG
- You must already be taking a stable dose of steroids
- The study coordinator will provide you a full list of requirements for participation.

How long will I be in the study?

You will be in the study for up to 52 weeks. Please ask the study coordinator to explain the details of the visit schedule.

What are the risks of the study?

Rituximab infusion may cause side effects:

- Flu-like symptoms such as fever, chills, weakness, muscle aches, tiredness, dizziness and headaches
- Low blood pressure
- Occasionally vomiting (anti-vomiting medication can be prescribed for prevention)
- Occasionally skin reactions such as soreness at infusion site, blisters or peeling of skin

Please ask the study coordinator to discuss rituximab infusion risks in more detail.

What are the benefits of the study?

You may or may not have improvement in your symptoms of weakness, difficulty swallowing, double vision and droopy eyelids. You may or may not be able to reduce your prednisone dose during the study. Others with myasthenia gravis may benefit in the future from what is learned from this clinical trial.

Will I be paid to take part in the research study?

You will receive about \$575 to help with travel and parking costs for the study visits (\$25 per visit).