

## **Frequently Asked Questions about the Rituximab in Myasthenia Gravis Study (NN103)**

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

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



### **Why is this study being done?**

We are doing this study to learn if rituximab vs. placebo is a safe and effective drug for people with myasthenia gravis (MG) who are taking prednisone allowing them to significantly reduce their prednisone dose. We will enroll 50 people in the study; 25 will receive the study drug (rituximab) and 25 will receive placebo (inactive salt-water).

### **What is Rituximab?**

Rituximab, the study drug, is a type of medicine known as a monoclonal antibody (MAB). It works by decreasing specific white blood cells called B cells. Scientists think these cells produce a reaction that causes MG symptoms.

### **How is Rituximab given?**

Rituximab (and the placebo) is given through a needle inserted into a vein in your arm called an infusion. Neither you nor your study doctor will know if you are receiving rituximab or the placebo.

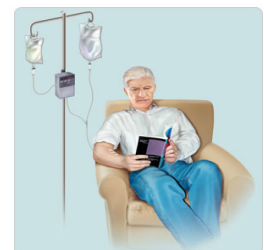
### **What do I need to tell my doctor before the infusion?**

Sometimes Rituximab can worsen heart disease and cause irregular heartbeats. The effect of the drug on pregnancy and unborn babies is unknown, so the drug cannot be used in women who are pregnant or breastfeeding. You should not take rituximab if you have had a reaction to it in the past.

### **What are the risks and possible discomforts from being in the research study?**

The Rituximab/placebo infusion may cause the following side effects:

- Possible immediate side effects (during infusion)
  - Flu-like symptoms such as fever, chills, weakness, muscle aches, tiredness, dizziness and headaches
  - Lower blood pressure
  - Nausea and/or vomiting (anti-vomiting medication will be prescribed to prevent this)
  - Possible allergic reactions such as skin rashes, itching, a feeling of swelling in the tongue or throat, irritations of nasal passages, wheezing and difficulty breathing. We will give you medications before the infusion to help decrease the risk of an allergic reaction.
- Late onset of side effects (after infusion)
  - Possible increase in feeling tired and difficulty breathing due to a decrease in the red blood cells that carry oxygen.
  - An increased risk of infection due to fewer white blood cells which fight infection.



### **How long will I take part in this research study?**

It will take 52 weeks to complete the study.

### **What happens while I'm in the research study?**

First, you will come in for a screening visit to find out if you are able to be in the study.

- This visit takes about 4 hours and includes the following:
  - We will ask you to provide us with demographic and medical history information
  - You will have a physical exam
  - We will test you for hepatitis and HIV
- You will receive a MG focused neurologic exam and complete a questionnaire
- A study staff member will draw about two tablespoons of blood from a vein in your arm

#### Study Drug Infusion Visits

- You will return to UC Davis for infusions every week for the first four weeks of the study. You will then return weekly for weeks 24-27. These infusions will take about 5 to 6 hours
- We will collect about two tablespoons of blood in the morning before you receive the study drug/placebo infusion
- A study staff member will take your vital signs during these infusions

#### Regular Study Visits

- You will come to UC Davis every four weeks throughout the study
- You will receive a myasthenia gravis focused physical exam and complete a questionnaire
- We will ask you about your current medication use and any side effects you may be feeling.
- The study staff will draw about two tablespoons of blood at each visit

### **What types of tests will I have during study visits?**

- We will measure your blood pressure, heart and breathing rates, and temperature at each visit.
- You will have a neurological exam (to check your senses, reflexes, strength, balance, and coordination) at the Screening Visit.
- We will perform several tests to measure your MG signs and symptoms. This will include questionnaires that ask about your quality of life and ability to perform certain daily activities. Other tests will measure the strength of your eye, face, neck, arm and leg muscles as well as your swallowing and speech as well as your respiratory function and grip strength.

### **Will I be paid to take part in this research study?**

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

### **Who do I call if I have questions about this research study?**

Please contact Randev Sandhu at 916-734-4303 or email [rssandhu@ucdavis.edu](mailto:rssandhu@ucdavis.edu) to talk about this research study.

You can also visit the NeuroNEXT website at [www.NeuroNEXT.org](http://www.NeuroNEXT.org) to learn more. This study is also listed at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under NCT # 02110706