AN INTRODUCTORY GUIDE FOR PATIENTS AND CAREGIVERS
Welcome to VIVACITY-MG

The VIVACITY-MG Study is a clinical research study for people with generalized myasthenia gravis (gMG). The purpose of this study is to determine whether the investigational drug is safe and effective in the treatment of this disease.

YOU MAY BE ELIGIBLE TO PARTICIPATE IF YOU:

• Are 18 years of age or older
• Have been diagnosed with myasthenia gravis
• Experience symptoms affecting more than just your eyes (e.g., limbs, neck, back, chewing, swallowing, speech, breathing)
• Are currently on a stable dose of MG-related medication(s)
• Have not received a thymectomy, rituximab (Rituxan®), or eculizumab (Soliris®) within the last 12 months

For a complete list of eligibility criteria and to see if you may be able to participate in the VIVACITY-MG Study, please speak with a member of the study team.
Myasthenia gravis (MG) is a chronic autoimmune neuromuscular disease which affects skeletal muscles that are responsible for eye movements, breathing and moving parts of the body, resulting in muscle weakness and fatigue.

All muscle movements are triggered by nerve cells. In healthy muscles, nerve endings transmit signals that are received by muscle receptors to cause muscle contraction. But in MG, the immune system mistakenly attacks those receptors by producing anti-receptor antibodies (most commonly acetylcholine receptor [AChR] or muscle-specific kinase, [MuSK] antibodies) that can block or destroy these muscle receptors, preventing the signals from effectively reaching the muscles.

Over time, this may lead to symptoms such as limb weakness, drooping eyelids, double vision, as well as difficulties with chewing, swallowing, speech and breathing.

While many patients with MG may be managed with current therapies, some patients may 1) fail to respond adequately despite multiple therapies, 2) not tolerate these therapies, and/or 3) have conditions that do not allow the use of these therapies. These patients may continue to experience profound muscle weakness and severe disease symptoms that limit their functions and their quality of life. Research is needed to develop the new treatment options for patients with MG.

That is why we’re conducting the VIVACITY-MG Study.
A Potential New Approach to Treating MG

In MG, the body’s immune system creates antibodies which block and attack the receptors between the nerve cells and the muscles – causing muscle weakness and fatigue. The investigational drug is being studied to see if it can lower the level of these harmful antibodies in the body, which may prevent them from blocking or destroying the muscle receptors.

Researchers believe the investigational drug may help improve nerve-to-muscle signals and muscle function, the clinical signs and symptoms of MG, and quality of life.

The investigational drug is delivered via infusion (a needle connected to a tube) and will be given along with standard treatment for MG.

Study participants will be randomly assigned to either a specific dose of the investigational drug or placebo (an inactive substance).

The chances of receiving the investigational drug are 80% (a four-in-five chance) and placebo are 20% (one-in-five chance). Study participants will have an equal chance of being assigned to any of the five study drug groups.

During the study treatment period, study participants will receive five infusions of their assigned study drug (every two weeks for eight weeks), along with study-related care and assessments. Each infusion will take approximately two hours.

The investigational drug is not approved by the U.S. Food and Drug Administration (FDA) or any other regulatory agency. It is not known if the investigational drug works or is safe. Your health may get better, worse, or not change at all. Please speak with your study doctor for more information about the potential risks and discomforts you may experience by participating in this study.

POTENTIAL RISKS AND BENEFITS
Study Participation
Overview

LENGTH OF PARTICIPATION
Approximately four months

NUMBER OF STUDY VISITS
Nine total visits
  • One screening visit
  • Six visits during study treatment period
  • Two follow-up visits

STUDY DRUG DELIVERY
Study drug will be administered via two-hour IV infusions every two weeks (5 total infusions)

INVESTIGATIONAL DRUG VS. PLACEBO
Study participants will be randomly assigned (like flipping a coin) to one of five study drug groups.
  • Four of the five groups (80%) will receive the investigational drug.
  • One of the five groups (20%) will only receive placebo (an inactive substance).

TESTS, ASSESSMENTS, AND PROCEDURES
In addition to receiving study drug, all study participants will regularly undergo a number of tests during study visits.
These are done to monitor study participants’ health and to help researchers determine the effects (if any) of the investigational drug.

OPEN-LABEL EXTENSION
Study participants in the VIVACITY-MG Study may have the opportunity to enroll in a long-term extension study, where they will all receive the investigational drug for an additional length of time at no cost.
It’s Time to Talk About Your Options

The study doctor, along with other doctors and healthcare professionals, is helping to conduct this study as part of their commitment to advancing treatment options for MG. What comes first, however, is your doctor’s commitment to you – and to helping you make the right choice about your care.

Participating in the VIVACITY-MG Study is completely voluntary. Before you decide whether or not you want to participate, the study doctor will review the potential risks and benefits of study involvement in detail and answer any questions that you may have. Even if you choose not to participate, your discussions with the study doctor may help you find your next step in managing MG.

Interested in learning more about the VIVACITY-MG Study? Speak with the study doctor today.