

What is Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)

CIDP is a rare condition that affects the peripheral nerves. These are the nerves outside your brain and spinal cord. Each nerve has a protective layer called the myelin. In people with CIDP, the immune system mistakenly attacks the myelin, leading to damage. As a result of this damage, communication between the nerves and the brain may be disrupted.

This can affect many parts of the body, but the feet and hands are involved most often. Common symptoms of CIDP include:

- Numbness of toes or fingers
- Loss of or reduced reflexes
- Difficulty walking
- Fatigue
- Muscle weakness and cramping in feet or hands
- Difficulties with main senses, including touch

The effects on a person's daily life can be significant. Basic tasks, such as getting dressed, eating, and lifting things, may become increasingly difficult. Although there is no cure for CIDP, it is treatable. However, it can also come back (relapse) after treatment. Research studies such as The MiGRATE Study are looking at all aspects of CIDP in hopes to bring potential treatments and enhanced quality of life for people living with this condition.

What are clinical studies?

Clinical research studies, also called clinical trials, look for ways to prevent, detect, and treat diseases and illnesses. They are designed to test the safety and effectiveness of study drugs so researchers may understand if these potential treatments can be used in the future.

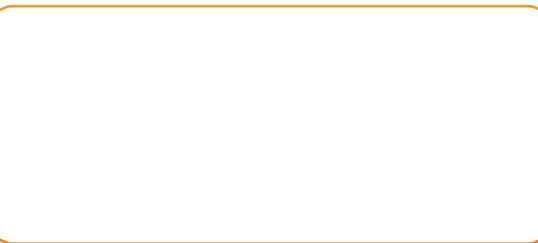
Before a clinical research study can begin enrolling study participants, it must be approved and monitored by an institutional review board (IRB) or ethics committee (EC), whose primary purpose is to protect the safety and rights of all study participants.



For more information about The MiGRATE Study, please visit:

theMigRATEstudy.com

You can also contact the study site below to talk with a member of the study staff.



To watch a short video about the study, please scan the code.



If this study isn't the right fit for you or your loved one, but you'd like to stay informed about future Takeda studies that may better suit your needs, we invite you to visit WeConnect. Explore our available studies, and if you don't see one that matches your needs, you can share your information with us to stay connected for future opportunities.

weconnectpatients.com

MiGRATE

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Paving the Way Forward for IgG Therapies

THE
MiGRATE
STUDY

What is The MIgGRADE Study?

The MIgGRADE Study is a clinical study of an investigational drug called TAK-881, which:

- Is being evaluated as a potential immunoglobulin G (IgG) treatment for Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)
- Is given as an infusion under the skin
- Has a higher IgG concentration, which means a lower infusion volume is needed
- Has the potential to shorten infusion times
- Is not approved by any regulatory authority for use outside of research studies like this one



Who can join?

You may qualify to participate in this study if you are at least 18 years of age and you:

- Have been diagnosed with CIDP, or possible CIDP
- Have responded to IgG treatment in the past
- Have been receiving the same IgG treatment for 12 weeks



You will also need to meet additional criteria, which the study doctor and staff will explain.

Why is this study being done?

In this study, TAK-881 will be compared to an approved IgG treatment called HYQVIA®. This will help us learn more about:

- How the body processes each of these study drugs
- What effects TAK-881 may have on CIDP
- How safe TAK-881 is and how the body tolerates it
- How the immune system reacts to TAK-881
- The infusion experience with each of these study drugs



How will I know if this study is right for me?

Joining a clinical study is a personal choice and should be an informed choice. Talk with your doctor and take the time you need to make the decision that is right for you.



Informed Consent Process

Before you decide if you want to join this study, you need to know what it involves. To help you make an informed decision, the study doctor and staff will:

- Give you an informed consent form that explains the study
- Review the informed consent form with you
- Answer any questions you may have

You can also talk with your doctor and family. Together you can decide if The MIgGRADE Study should be part of your CIDP journey.

How long is the study?

The total time you may be involved in this study is up to 4 years. However, you can choose to stop at any time, for any reason. Your choice will not impact the medical care you receive outside of the study.



What are the costs for joining the study?

Study drug infusions and study visits will be provided at no cost to you. You may also be reimbursed for pre-approved expenses related to your study participation.



What happens if I qualify for the study?

If you qualify and choose to participate, you will receive study treatment in 5 periods, as briefly described below. Infusions in each part of the study will be every 3 or 4 weeks. You will be asked to attend study visits with the study doctor and staff, so your health is monitored closely.

1. Screening Period

If you sign the informed consent form, the study doctor will determine if you qualify for the study. This will be based on a screening process that includes:

- A review of your medical history and your IgG treatments
- Medical procedures and tests to assess your health and your CIDP
- Surveys about how CIDP affects your daily life

2. HYQVIA Ramp-up Period

For those who aren't already on HYQVIA, we will ask you to transition off your current IgG treatment into HYQVIA until you've reached your first full dose. If you have been receiving treatment with HYQVIA, you will skip the ramp-up.

3. HYQVIA Dosing Period

You will be dosed with HYQVIA for up to 20 weeks. Infusions will be administered at the study clinic by a healthcare provider.

4. TAK-881 Period

Next, you will have TAK-881 infusions for 24 weeks. Infusions will be administered at the study clinic by a healthcare provider. At the end of this part of the study, you or a caregiver may administer your infusions at the clinic after being trained.

5. TAK-881 Extension (3 years)

You will continue to have TAK-881 infusions for approximately 3 more years. You or a caregiver will administer your infusions at home if the study doctor agrees that it is safe and appropriate.