

*Thank you for considering
the Vitalize Study.*

What is CIDP?

CIDP is an autoimmune disease that affects the nerves. Symptoms of CIDP may include:

- Tingling or loss of feeling in your arms and legs (can't feel a pin prick).
- Weakness in your arms and legs.
- Loss of reflexes, balance, and/or the ability to walk.

What is the purpose of this study?



We want to understand whether the study medicine can improve the symptoms of CIDP and their impact on daily activities.

Research studies help to improve the way doctors treat and prevent illness. This brochure explains a research study being done to learn more about a potential new treatment for CIDP.

Being in a study is completely voluntary. If you decide to join the study and then change your mind, you can leave at any time. Although your condition may or may not improve during the study, your participation could contribute to finding better ways to treat this challenging condition.

If you are interested in learning more, please follow the links below:

[SanofiStudies.com](https://www.sanofi.com/studies)
clinicaltrials.gov









Who can join the study?



You may be able to join the study if you meet these and other criteria:

- Are at least 18 years of age
- Have been diagnosed with CIDP
- Are being treated with a stable dose of immunoglobulins that are helping your disease symptoms, but not fully

Participating in a research study may not only change your personal journey, but may also help patients in the future.

A research study for people with chronic inflammatory demyelinating polyneuropathy (CIDP)

What happens during the study?

The study lasts about 2 years and has 4 parts.



Screening

Up to 8 weeks
1 clinic visit

You'll have health checks and tests to **see if you qualify** for the study.

Treatment Part A

24 weeks (about 6 months)
At least 5 clinic visits

You'll take the **study medicine OR continue immunoglobulin infusions** and visit the study clinic. The study staff will call you between clinic visits.

Treatment Part B

24 weeks (about 6 months)
At least 4 clinic visits

You'll take the **study medicine (NO immunoglobulin infusions)** and visit the study clinic. The study staff will call you between clinic visits.

Follow-up

55 weeks (about 1 year)
At least 1 clinic visit

You'll have a **final checkup** after you stop taking the study medicine. The study staff will also check on you by phone.

What is the study treatment?



You could be placed into 1 of 2 treatment groups. Group 1 will take the study medicine. Group 2 will continue with their usual immunoglobulin infusions.



Study medicine

Not currently approved by Health Canada for treating CIDP but can be used for research purposes



The study medicine blocks a protein in the blood that is believed to attack the body's normal cells and contribute to the development of diseases such as CIDP.



The study treatment is a weekly injection. After receiving the first dose intravenously (into a vein) at the study clinic, you will come back to the clinic a week later to receive the first subcutaneous (under the skin) injection. During that visit you will be trained on how to inject yourself at home.

What kinds of procedures can I expect?

At study visits, there will be health checks and tests to monitor your health and for research purposes. You will not have every test at each visit.



Informed consent



Health and medicine review



Vaccinations (if applicable)



Blood samples



Urine sample



Pregnancy test (if applicable)



Vital signs (blood pressure and temperature)



Physical and neurological exams



Electrocardiogram heart test



Disease and health questionnaires



Study diary collection

What else should I know?



Before any study procedures can begin, you first need to agree to join the study by reading and signing the Informed Consent Form.

If you qualify for the study, you will receive study-related treatment, tests, and doctor visits at no cost to you.