What are clinical research studies?

Clinical research studies help scientists and doctors explore whether a medical strategy, device, drug, or therapy is safe and effective for people. These studies are important because they help identify which medical approaches work best for specific illnesses in specific groups of people.

Participation in clinical research is voluntary, and participants can leave a study at any time. If you decide to join the RiNeuD study, there is no guarantee that the study medication will improve your DPN, but what researchers learn may lead to better medications in the future.

RiNeuD

For more information about the RiNeuD study, contact:

Is diabetes causing you pain? Tingling? Numbness?

If *yes*, you may have a condition known as painful diabetic peripheral neuropathy (painful DPN). Learn about the RiNeuD clinical research study designed to find out if a potential new medication can help people with painful DPN.

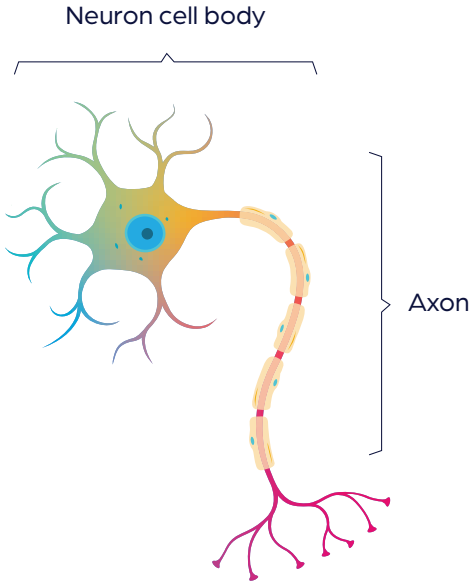
RiNeuD

What is the RiNeuD study?

The RiNeuD study is a clinical research study for people who have type 1 or type 2 diabetes that has led to painful DPN. The goal of the RiNeuD study is to find out if the study medication can provide relief from the pain, tingling, and numbness associated with painful DPN. The study medication may be able to restore cells, called neurons, that transport messages between the brain and other parts of the body.

More about neurons

Neurons are cells that carry messages to and from the brain. Neurons that connect to the hands and feet are some of the longest cells in the body because the hands and feet are the farthest that a message must travel to and from the brain. The neurons' message transportation pathways, called axons, are very important. With painful DPN, the axons are damaged, so the brain receives incomplete messages and interprets them as pain, tingling, or numbness.



What is the study medication?

The investigational* study medication, ricolinostat, is designed to reduce pain, tingling, and numbness associated with painful DPN. It is expected to work by restoring the message transportation pathways that neurons use to communicate between the brain and other parts of the body.

**Investigational* means that ricolinostat has not been approved by the US Food and Drug Administration (FDA) to be used outside of clinical research.

Who can join the study?

You may be able to join the RiNeuD study if you meet the following study requirements*:

- Between 18 and 80 years of age
- Diagnosed with diabetes (type 1 or type 2) at least 6 months ago
- Have pain, tingling, numbness, or weakness in the hands, legs, or feet

*Other study requirements will apply.

RiNeuD

What can study participants expect?

Study participation will last about 8.5 months and will include the following periods:

- **Screening period** (4 weeks) – You will have study assessments and procedures to find out if you can join the study.
- **Single-Blinded Pain Recording period** (2 weeks) – You will be assigned at random (like a coin flip) to receive either the study medication or placebo (no active ingredients). *Single-blinded* means that you will not know which you receive, but the study doctor will know. You will drink the study medication or placebo every morning and record your pain levels in an electronic study diary. You will attend 1 visit at the study center and receive 1 phone call.
- **Double-Blinded Study Medication period** (12 weeks) – You will be re-assigned to receive either the study medication or placebo. *Double-blinded* means that neither you nor the study doctor will know which you receive. You will drink the study medication or placebo every morning and record your pain levels in the study diary. You will visit the study center 4 times and have study assessments and procedures.
- **Open-Label Safety period** (12 weeks) – You will take the study medication with no chance of receiving placebo. You will drink the study medication every morning and record your pain levels in the study diary. You will visit the study center 5 times and have study assessments and procedures.
- **Follow-up period** (4 weeks) – After you stop taking the study medication, you will attend 2 visits at the study center, so the study doctor can check your health.