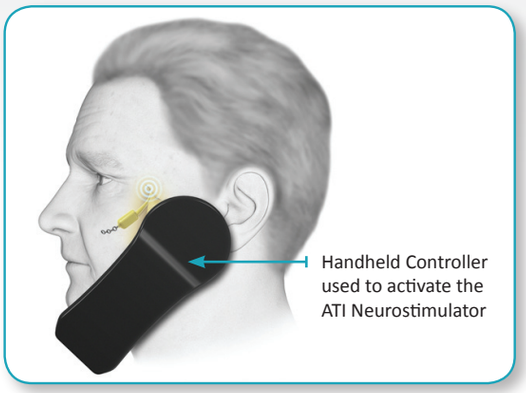
The Pathway CH-2 Study

Study Overview

What is the ATI™ Neurostimulation System?

The ATI Neurostimulation System is an investigational device designed to provide targeted, on-demand relief of chronic cluster headache. The ATI System works in conjunction with the sphenopalatine ganglion (SPG) – a nerve bundle located behind your nose that is known to play a major role in severe headaches. For decades, doctors have focused on the SPG for a variety of pain relief procedures.

The ATI Neurostimulation System is designed to provide direct, local stimulation to the SPG to interrupt and block nerve signals that cause cluster attack pain. The ATI Neurostimulator is smaller than an almond, and placed through a minimally-invasive oral procedure (small incision in your gum, leaving no visible scars). It is placed near the SPG nerve bundle, on the side of your face affected by cluster headaches. Once placed, you can control your own stimulation as needed by turning on the Remote Controller and holding it to your cheek. To stop the stimulation, simply remove the Controller from your cheek.



Study Summary

Screening Evaluation

To be eligible for the Pathway CH-2 Study, you must meet specific study criteria. These criteria have been designed to identify those individuals who are the most suitable candidates for the study. During the screening evaluation, your study doctor will check your overall health and will review your cluster headache symptoms and treatment history. You will also have a CT x-ray of your head, and will be asked to complete several questionnaires about your cluster symptoms and overall quality of life.

ATI Neurostimulator Placement & Study Periods

If you pass the screening evaluation and wish to continue with the study, you will be scheduled for your oral procedure to implant the ATI Neurostimulator. Depending on your doctor's discretion, you may be discharged the same day as your procedure, or you may stay in the hospital for one or two days. As a Pathway CH-2 Study participant, on the day of your procedure you will be assigned to one of two treatment groups - the two groups will receive different types of stimulation, and you will have a 50-50 chance of being in either group.

- **Parameter Adjustment Period (12 weeks):** Twelve (12) weeks after placement, your doctor will program your ATI Neurostimulator and you will be taught how to use it and control your level of stimulation. This will begin a 12-week period called the "Parameter Adjustment Period" where you will visit your study doctor's office regularly and provide feedback about your experiences. Your study doctor may change the settings of your neurostimulator during this period based on your feedback about what you feel with the stimulation.

- **Experimental Period (4 weeks):** Following the Adjustment Period your doctor will program your neurostimulator to the most appropriate settings for you, and the settings will not be changed for the next 4 weeks - this period is called the "Experimental Period." Each time you use the remote controller during this time, you will receive stimulation according to the settings selected by your doctor, but you can still adjust the stimulation level as needed using a button on the remote controller. During this period your doctor will also give you specific instructions about when you can use stimulation.

- **Open Label Period & Long Term Follow-Up:** Following the Experimental Period, your neurostimulator settings may be changed if needed. You will visit your study doctor regularly (about once every 8 weeks) until the 1 year anniversary of your procedure. During these visits, your doctor can adjust your stimulation settings if necessary. Following your 1 year anniversary, you will continue to meet with your doctor once every 6 months, up until your 3 year anniversary of your procedure. At your final visit, you and your doctor will decide the best treatment for you. You can continue using the ATI Neurostimulator, have it removed, or you can decide to stop neurostimulation therapy but leave the neurostimulator in place (in case you want to re-start therapy at a later time). If you have the neurostimulator removed, this is done through a short, outpatient procedure.

The Pathway CH-2 Study

Frequent Questions

1. What is the ATI™ Neurostimulation System?

The ATI Neurostimulation System is an investigational device designed to provide targeted, on demand relief of chronic cluster headache. The ATI Neurostimulator is placed through a minimally-invasive oral procedure (small incision in your gum, leaving no visible scars), near the SPG nerve bundle – known to play a major role in severe headaches. Once placed, the ATI Neurostimulation System allows for on-demand stimulation of the SPG to interrupt and block nerve signals that cause cluster attack pain.

2. How is the stimulation controlled?

Once the ATI Neurostimulator is placed, you can control your own stimulation as needed by turning on the Remote Controller and holding it to your cheek. To stop the stimulation, simply remove the Controller from your cheek.

3. Has the ATI Neurostimulation System been used before?

Yes, the ATI Neurostimulation System has been used in previous controlled clinical studies, and is commercially available in select European countries.

4. Can I receive the ATI Neurostimulation System without joining the Pathway CH-2 Clinical Study?

No, the ATI Neurostimulation System is an investigational device in the U.S. and is currently only available through the Pathway CH-2 Clinical Study.

5. Can I have the ATI Neurostimulator removed if I choose?

Yes, the ATI Neurostimulator can be removed through a short, outpatient oral procedure (simpler than the original implant procedure).

6. What will I need to do if I take part in the Pathway CH-2 Study?

If you qualify and choose to join the Pathway CH-2 Study, you will be asked to:

- Attend regularly scheduled visits with your study doctor and staff
- Follow the instructions your study doctor provides (as it relates to both your neurostimulator therapy and headache medications)
- Immediately report any issues or concerns to your study doctor

Thank you again for your interest in the Pathway CH-2 Study. If you have any questions, please do not hesitate to contact us.

Caution: The ATI Neurostimulation System is an investigational device and is limited by United States law to investigational use.