The ACCURATE Clinical Study

Study Overview

What is the Axium™ Neurostimulator System?

The sensation of pain is felt when your body sends a pain signal to your brain. With chronic pain, that pain signal can continue even after the original cause of the pain has been treated and resolved. **Neurostimulation** is a technique for treating chronic pain that uses a small implanted system called a neurostimulator. The neurostimulator delivers mild electrical signals to the nerves in your spinal cord. These signals replace the original pain signal with a tingling or massaging feeling, covering the specific areas where you feel pain.

The Axium™ Neurostimulator System is an investigational device for the treatment of chronic pain. The Axium System is a form of neurostimulation that targets a specific branch of the spinal cord called the Dorsal Root Ganglion (DRG). The DRG acts like a traffic light that controls when sensations enter the spinal cord. It is believed that stimulation of the DRG can serve as a stoplight, preventing pain signals from traveling to the brain. Like other neurostimulator systems, the Axium System comes with a handheld "remote control" that lets you adjust the strength of the stimulation, and turn the stimulator on or off.

About the ACCURATE Clinical Study

Pain centers throughout the U.S. are currently participating in the ACCURATE Clinical Study. The study is for individuals who suffer from chronic pain affecting their lower limbs (such as the leg, foot, or groin). Participants in the ACCURATE Study will be treated with one of two neurostimulator systems – either the Axium System or a similar, commercially available system.

Screening Evaluation

To be eligible for the ACCURATE 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 perform a physical and neurologic exam and will ask you about past treatments for your pain. Your doctor may also request an MRI scan of your spine. In addition, you will complete several questionnaires to measure the severity of your pain and its impact on your quality of life.

Trial Stimulation Phase

If you pass the screening evaluation and wish to continue with the study, you will be randomly assigned (by chance) to one of two study groups – the Axium Group (1 in 2 chance) or the Control Group (1 in 2 chance). Your group assignment determines which neurostimulator system you will receive – the Axium System or a similar, commercially available system. There are minimal differences between the two systems.

An important feature of all neurostimulator systems is that you can try the therapy for a period of time before deciding to have it implanted. Once you are assigned to a study group, you will be scheduled to undergo an outpatient procedure to have the temporary system placed. You will then be able to try the temporary system for up to 30 days. During this time, you will be in regular contact with your study team to evaluate how the temporary system is working. If after the trial period both you and your doctor are satisfied with the pain relief, you may choose to have the system implanted through a minimally-invasive, outpatient surgical procedure.

Implant and Follow-Up Phase

If you proceed to this phase of the study, you will have the neurostimulator system fully implanted under your skin during an outpatient surgical procedure. The neurostimulator is about the size of a box of matches, and is typically placed in the upper buttocks or abdomen. Following placement of the system, you will meet with your study doctor about 5 times over the next 12 months. During these visits, your doctor will check how you are doing and you will complete questionnaires to measure your pain and quality of life. Following your 12-month visit, you will meet with your study doctor once a year for up to the next 4 years to further monitor your health and experiences.

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Frequently Asked Questions

1. How common is neurostimulation therapy?

Neurostimulation is a well-established therapy for treating chronic pain. FDA-approved neurostimulators have been used to treat over 300,000 patients. The Axium System is investigational, and not yet approved by the FDA.

2. What does neurostimulation therapy feel like?

People describe the sensation differently. Some people describe neurostimulaton as a tingling sensation or massaging pressure over the painful area. Others have reported that they simply feel the absence of pain. Your study doctor will be able to discuss these and other experiences with you.

3. Will the implanted neurostimulation system give the same relief as the temporary system?

The goal is that the implantable system will give as much or greater pain relief as the temporary system. However, pain relief can differ. Your study doctor will optimize your therapy for the greatest pain relief possible.

4. Can I stop my neurostimulation therapy?

Yes. If your pain has become resolved, or you decide neurostimulation is not the right therapy for you, the device can be turned off or surgically removed at no cost to you.

5. How do I know if I am eligible for the ACCURATE Clinical Study?

The ACCURATE Clinical Study is for individuals who suffer from chronic pain affecting their lower limbs (such as the leg, foot, or groin) who have not had lasting success with other treatments.

To be eligible for the ACCURATE Clinical 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. If you are interested in possibly participating in the ACCURATE Clinical Study, your study team will help assess your eligibility.

6. Why is there a Control Group?

One purpose of the ACCURATE Clinical Study is to compare the safety and effectiveness of the investigational Axium™ Neurostimulator System to a similar, commercially available system. There are minimal differences between the two systems, and your study doctor will be able to discuss these with you in detail.

7. Are there any costs involved in the ACCURATE Clinical Study?

Participants in the ACCURATE Study will receive their neurostimulator system, as well as any examinations or visits required for the study at no cost.

8. How long will the study last?

Following implantation of your neurostimulator system, you will return to your study doctor's office about 5 times over the next 12 months. During these visits, your doctor will check how you are doing and you will complete questionnaires to measure your pain and quality of life. Following your 12 month visit, you will meet with your doctor once a year for up to the next 4 years to further monitor your health and experiences.

9. Who is sponsoring the ACCURATE Clinical Study?

The study is being sponsored by Spinal Modulation, Inc., a global medical device company headquartered in Menlo Park, CA (www.spinalmodulation.com).

10. What are the potential risks associated with the ACCURATE Clinical Study?

The Axium Neurostimulator System is an investigational device that has risks that must be weighed against the potential benefits. The potential risks are similar to those of other surgically implanted neurostimulator devices, and will be fully outlined in the informed consent document. Consult a study doctor to discuss your medical options, and the potential benefits and risks of taking part in this study.

Thank you for your interest in the ACCURATE Clinical Study. If you have any questions, please do not hesitate to contact us.

Lisa Brooks, PhD
Pain Clinic of Monterey Bay
(831) 684-0600
LBrooks@painclinicofmontereybay.com

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