The ECAP Clinical Study

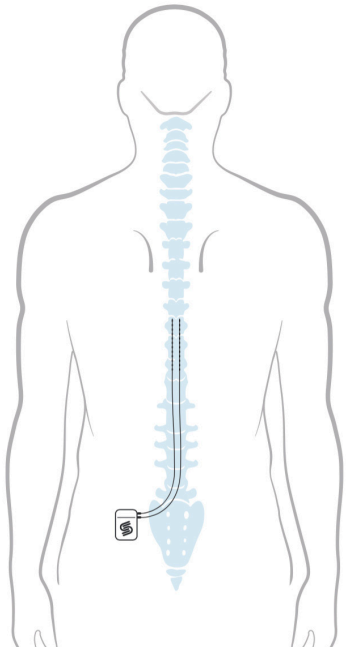
Study Overview

What is Spinal Cord Stimulation (SCS)?

We feel pain when our body sends a signal to the brain. **Spinal cord stimulation (SCS)** helps mask or interrupt these pain signals before they reach the brain. This is done using a small implanted device that sends mild pulses of energy to the spinal cord. Most SCS systems also come with a handheld remote control that lets you adjust the strength and location of therapy, or even turn it off.

What is the Evoke Closed-Loop SCS System?

The Evoke® Closed-Loop SCS System is a new type of SCS, and is currently being evaluated in the U.S. as an investigational device through the ECAP Clinical Study. Evoke is the only SCS system designed to measure the spinal cord's response to stimulation and automatically make adjustments intended to maintain a consistent level of pain therapy.



The Evoke SCS System sends mild pulses of energy to the spinal cord to interrupt pain signals before you feel them.

About the ECAP Clinical Study

Doctors at select U.S. centers are accepting participants for a new clinical study to evaluate the Evoke Closed-Loop SCS System for the treatment of chronic back and/or limb pain.

Step 1: Screening Evaluation

To be eligible for the ECAP Clinical Study you must meet specific criteria. These criteria have been designed to identify individuals who are suitable candidates for the study. During the screening evaluation your study doctor will perform a routine physical exam and will ask you about past medications and treatments for your pain. In addition, you will be asked to complete several questionnaires to measure the severity of your pain and its impact on the quality of your life. If you pass the Screening Evaluation and wish to continue with the study, you will proceed to the Trial Stimulation Phase.

Step 2: Trial Stimulation Phase

An important feature of the Evoke Closed-Loop SCS System is that you can try it for a few days or weeks to decide whether it is right for you. The temporary Evoke SCS System is placed in a simple, outpatient procedure that is completely reversible. You doctor will use a needle to place thin, flexible wires, called leads, in your back (no incision required). The leads connect to the external temporary device. After the trial period you and your doctor will evaluate your response to treatment, and decide whether to have the Evoke SCS System implanted. This is done through another reversible surgical procedure to place the Evoke SCS device beneath the skin (typically in the upper buttocks).

Step 3: Implant and Follow-Up Phase

If you have the Evoke SCS System implanted, you will be asked to come in for a post-surgery follow-up and for 6 study visits spread out over the course of 2 years. During these study visits, your doctor will check how you are doing and you will complete questionnaires to measure your pain and quality of life.

EVOKE™

The ECAP Clinical Study

Frequently Asked Questions

1. How common is Spinal Cord Stimulation (SCS)?

Approximately 50,000 people receive SCS systems each year to manage their chronic pain.[1]

2. How is the Evoke SCS System different from other SCS systems?

Unlike conventional SCS systems, the Evoke Closed-Loop SCS System is designed to measure your body's response to stimulation and make automatic, real-time adjustments intended to maintain a consistent level of pain therapy. The system is designed to maintain therapy near the preferred level set by you. If needed, you can also adjust your stimulation level using your remote control.

3. How do I know if I am eligible for the ECAP Clinical Study?

If you struggle with chronic back and/or limb pain you may be eligible for the ECAP Study. If you are interested in possibly participating in the study, your study doctor and team will help assess your eligibility.

4. How often will I be expected to come into the clinic? How long will the study last?

As part of your participation in the ECAP study, you are required to attend 6 study follow-up sessions. These follow-up visits will take place 1 month, 3 months, 6 months, 12 months, 18 months, and 24 months after your implant. During these study visits, your doctor will check how you are doing and you will complete questionnaires to measure your pain and quality of life.

5. Will I be able to control my stimulation while at home?

Yes, you will be provided with your own remote control so that you can adjust the level of therapy at home. The Evoke Closed-Loop SCS System is designed to measure your body's response to therapy and automatically adjust to maintain a consistent level of pain therapy.

6. Is it easy to recharge the stimulator?

Yes, the Evoke Closed-Loop SCS System is charged using the Evoke charger kit. The Evoke charger is placed over the stimulator (on top of your clothes) and held in position until your battery is fully charged.

Recharging the Evoke System can be incorporated into your routine, for example, while watching your favorite television show.

7. Who is sponsoring the Evoke Clinical Study?

The study is being sponsored by Saluda Medical Pty, Ltd., a medical device company with offices in the United States, Europe, and Australia (www.saludamedical.com).

8. What are the potential risks associated with the ECAP Clinical Study?

The Evoke SCS System is an investigational device. The potential risks are similar to those of other surgically implanted neurostimulator devices. These risks and any additional risks associated with study procedures are fully outlined in the Informed Consent document.

Prior to joining the study, your doctor will discuss the risks and potential benefits with you in detail to help you decide whether this study may be right for you.

9. Can I stop or reduce other pain treatments once my Evoke SCS System is implanted?

The Evoke SCS System works as part of your pain treatment. All changes to your pain treatments, including reducing medication, should be discussed with your doctor prior to making any changes.

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

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.

1. Global Spinal Cord Stimulation Devices Market. iHealthcareAnalyst, Inc. https://www.ihealthcareanalyst.com/global-spinal-cord-stimulation-devices-market

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