

Will I receive any medical benefit?

You may experience relief of shoulder pain from participating in this study. No guarantee of benefit or any other result can be made. Your participation may help in the understanding of post-stroke shoulder pain and may lead to additional studies in the future.



What risks are associated with participating in the study?

There are risks associated with participation in the study. Dr. O'Dell, the study doctor, and his staff will review all of the risks with you and answer any questions you have before you agree to be in the study.

Will there be any costs to me if I participate?

Your participation in this research study will be done at no cost to you. You will be paid a small amount at each study visit to cover your costs such as transportation, parking, meals, and to compensate you for your time.

I am interested. Who should I talk to?

Dr. O'Dell, the study doctor, can give you more information on the study. You can also call his study coordinator:

Grace Kim
212-746-1356



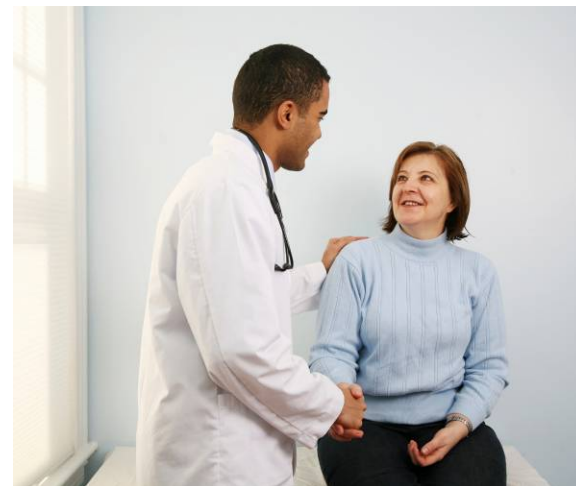
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CAUTION: Investigational Device. Limited by US law to investigational use only.

The SPR™ System (including components and/or methods thereof) is protected under one or more of United States Patent numbers ©113,812; ©121,308; D581,530; D559,987; 6,845,271; and 7,239,918, as well as corresponding international patents. Additional patents are pending.

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IRB APPROVED
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12.20.10

Volunteers wanted:

For participation in a clinical study on

**POST-STROKE
SHOULDER PAIN**

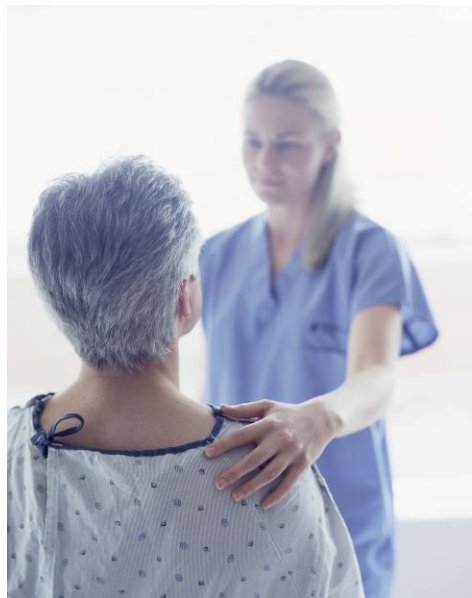
Informational Pamphlet

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We Need Your Help...

to learn more about reducing shoulder pain in people who have suffered a stroke.

If you are one of the millions of people in the United States who suffer from shoulder pain following a stroke, you may be eligible to participate in a study.



This study may help doctors understand whether low levels of electricity delivered to shoulder muscles may reduce shoulder pain in people who have suffered a stroke.

What is the SPR™ System?

The SPR System is an investigational device that is being studied for the relief of post-stroke shoulder pain. The System uses electrical stimulation and includes a Trial Stage (where a temporary system is used to see if you may benefit from this type of therapy) and an Implant Stage (where a small device is implanted under your skin in your chest).

What is post-stroke shoulder pain?

Post-stroke shoulder pain is pain in the shoulder area that starts after a person has had a stroke. Some doctors believe shoulder pain develops after stroke because of weakness of the shoulder muscles.

How does the SPR System work?

The SPR System delivers mild electrical stimulation to the muscles in the shoulder where you feel pain. Electrical stimulation is used in many medical devices, such as pacemakers. This study will evaluate the effect of electrical stimulation on shoulder pain.

What does stimulation feel like?

When stimulation is sent to your shoulder muscles, it may feel like your muscle is moving, or tightening.

How is the SPR System implanted?

First, a temporary wire is placed in your shoulder and connected to a device outside of your body that makes electrical stimulation. You will use this temporary system for six weeks. Afterwards, you and the study doctor will decide if you may benefit from long-term stimulation. If you both agree that the SPR Implant System is right for you, a surgeon will surgically implant a device that makes electrical stimulation and a wire that delivers this stimulation to your shoulder.

Who can participate in this clinical study?

If you are over the age of 21, it has been six months since your stroke, you experience shoulder pain, and you have tried other therapies for your shoulder pain, you may be eligible.

How long is the clinical research study?

The study lasts about 3 years and includes 15 visits to the study doctor and 6 telephone calls from study staff.

How do I know if the SPR System is right for me?

If you have not had success with (or could not tolerate) other treatments for your shoulder pain, the SPR System may be a good option for you. Talk with your doctor to decide if the SPR System may be right for you.