

IRB #: IRB16-00172- Multimodal Treatment for Hemiplegic Shoulder Pain

Study information Sheet

Sponsor / Study Title: **National Institute of Child Health and Human Development (NIH) / Multimodal Treatment for Hemiplegic Shoulder Pain (PNS + PT for HSP)**

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KEY INFORMATION:

You are invited to take part in a research study. Research studies are voluntary and include only those who wish to participate. This research study is studying SPRINT PNS System as a possible treatment for Hemiplegic Shoulder Pain. National Institute of Health is sponsoring this research study.

The main reason you may want to join this study is you have tried other treatments for hemiplegic should pain, but they have not worked for you. The standard of care for treating shoulder pain is to try several options, most

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commonly including medications, injections and therapy. Treatments such as medications and injections may be effective for only a short time or may have unwanted side effects. Alternatively, therapy is one of the most commonly prescribed treatments and is accepted as effective by doctors treating shoulder pain, but it does not work for everyone. Another promising treatment is the use of electrical stimulation (small levels of electricity) to reduce shoulder pain, but it also does not work for everyone. However, both therapy and electrical stimulation appear to be effective for longer periods of time with fewer side effects than other treatments.

Some reasons you may not want to join this study follow:

- You may or may not receive the study intervention.
- The physical therapy combined with the device used in this study is experimental. Experimental means its safety and usefulness have not been proven.
- There are risks associated with needle insertion for the Lead placement.
- There are risks for skin irritation, infection or inflammation at the Lead exit site.
- The risks to a pregnant woman or unborn child are unknown.

The purpose of this study is to evaluate the effect of therapy and/or electrical stimulation in different combinations to reduce post-stroke shoulder pain.

This study is relevant to you because you have hemiplegic shoulder pain.

It is important for you to know that regardless of the type of treatment you receive for the study, you will have a procedure to place a small wire (called a "Lead") through your skin into a muscle in your upper arm.

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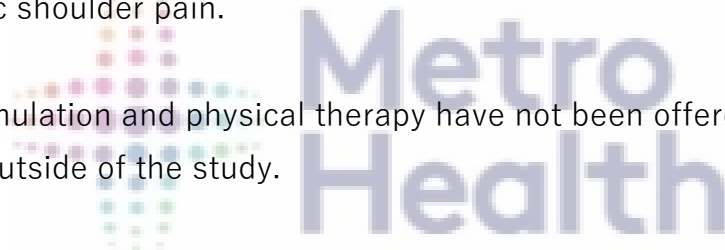
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The types of information collected over several visits during this study include the use of surveys to understand how you feel and how your shoulder pain impacts various aspects of your life; as well as assessments to measure strength and movement of your arm and shoulder. Other assessments will measure your sensitivity to pain.

There will be a total of 18 study visits over approximately a 7-month period. There will also be 1 telephone contact for the study and one clinical x-ray of your shoulder. The study visits will include 8 therapy visits.

Participating in this study may provide an alternative, successful treatment for hemiplegic shoulder pain.

Electrical Stimulation and physical therapy have not been offered together as a treatment outside of the study.



Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study we can schedule an eligibility visit to determine if you will meet the criteria.