What do I have to do to participate?

If you have questions about the study,
or are interested in participating, please visit:

http://www.mycancerpain.org

and contact your nearest treatment center.

Do you suffer pain caused by cancer that has spread to the bones?

Introduction

Doctors at various hospitals are participating in a clinical trial studying the use of a new treatment for the palliation (pain relief) of painful bone metastases (tumors) using Magnetic Resonance guided Focused Ultrasound Therapy. This is a completely non-invasive (without surgery) therapy to relieve pain. The focused ultrasound waves generate sufficient heat to destroy the pain causing nerves in the bone surface surrounding the tumor. The surface of normal bone will not be heated or affected. Magnetic Resonance Imaging (MRI) will be used not only to pinpoint the focused ultrasound heat deposition but also to continuously monitor the tissue temperature changes in real time. Ultrasound waves pass through skin and into the body, so no incisions or inserted probes are needed. Other studies have shown that the focused ultrasound device presents a very low risk to patients and is potentially an effective non-invasive means of relieving pain caused by bone metastases.

Who is eligible?

- Patients who have been diagnosed with bone metastases and for whom radiation therapy is not an alternative
- Up to three painful bone metastases with one much more painful than the others
- Able to undergo MR imaging exam

What is the cost?

There is no cost to the patient for this study.

How does the treatment work?

The treatment is MR guided Focused Ultrasound (MRgFUS). The focused ultrasound destroys the outer membrane of the bone that contains the pain causing nerves. This is done while you are having an MRI so that the bone tumor can be visualized precisely. The focused ultrasound is done from the outside of your body. The ultrasound waves are focused down onto a small area of the painful bone. This causes the bone surface to heat up which destroys the tissue. The focused ultrasound is then moved to an area next to the treated location and this new area is treated. This process is repeated several times until the nerves in the bone surface of the painful bone tumor are destroyed.
You will be given pain medication and light sedation to prevent the procedure itself from being too painful.

How long does the procedure last?

The entire MRgFUS procedure will last up to 2-3 hours.

What are some of the risks or side effects to the procedure?

While this is an experimental procedure, there are no known serious side effects of the treatment itself. The focused ultrasound treatment could cause some pain, a skin burn, or fever. There is the possibility of damage to other tissues but this is minimized through the use of MR imaging during the treatment to visualize the exact location of the focused ultrasound. You could have an allergy to the MRI dye or the medication for pain. There may be other risks that your doctor will discuss with you.

What are the benefits for your participation?

This is an opportunity to participate in a clinical trial for the relief of painful bone metastases. This experimental treatment may be successful in relieving the pain caused by a bone metastasis. If the study proves successful, this technology would serve as an additional means of relieving the pain caused by bone metastases. Your help could benefit other patients with this condition.

How long will I be in the study?

You will be in the study for up to 7 months. During this period, there may be visits to optimize your pain medication and a total of 7 phone and office appointments to monitor your health and the success of the treatment in relieving your pain from the treated bone metastasis.

What is new about this treatment?

This treatment is a non-surgical method to relieve pain caused by a bone metastasis. The treatment involves the use of MR-guided focused ultrasound waves to heat up the outer membrane of the bone that contains pain causing nerves. The bone surface is heated up one spot at a time until the surface of the bone in the area of the bone metastasis is destroyed. No incisions or probes are required. Previous studies have shown that the focused ultrasound device presents a very low risk to patients.