



What do I have to do to participate?

If you have questions about the study, or are interested in participating:
please visit
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 an experimental procedure for the palliation (pain relief) of painful bone metastases (tumors) using **Magnetic Resonance guided Focused Ultrasound Therapy**. This is a non-invasive (without surgery) procedure intended 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. Experience with the focused ultrasound device for other conditions shows a very low risk. We are doing this investigation to find out if focused ultrasound for pain palliation presents a similar low risk. This procedure may potentially be 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 Patients
- ▶ Able to undergo MR imaging exam

What is the cost?

There is no cost to the patient for this study

How does the procedure work?

The procedure 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 precisely seen. 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 heated location and this new area is heated. This process is repeated several times until the nerves in the bone surface of the painful bone tumor are destroyed.

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?

Based on all previous studies, the focused ultrasound procedure could cause some pain, skin burn, or fever. There is the possibility of damage to bowel, bladder, or other tissues but this is minimized through the use of MR imaging during the procedure 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.

Lying in the scanner for 2-3 hours may cause discomfort for which you will be treated during the course of the procedure.

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 investigation may be successful in relieving the pain caused by a bone metastasis, but there may be no benefit to you or may have some side effects. 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 8 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 procedure in relieving your pain from the bone metastasis. You will be assigned by chance to the MRgFUS or a sham group (no MRgFUS). Although patients who are in the sham group may be offered MRgFUS later in the study, we cannot guarantee that everyone in the study will receive MRgFUS.

How is this procedure different from available treatments?

This procedure is a non-surgical method to relieve pain caused by a bone metastasis. The procedure involves the use of MR-guided focused ultrasound waves to heat up the outer layer 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.