Bone cancer patients needed for study of potential pain treatment

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(Medical Xpress) -- People with cancer that has spread to their bones are being recruited by Stanford University School of Medicine researchers for a clinical trial that will assess the use of ultrasound to alleviate pain.

The trial is investigating how effectively a device called ExAblate 2000 — which emits high-intensity, focused ultrasound waves — can relieve the pain in bones that have been invaded by cancer. “If you imagine a magnifying glass concentrating sunlight to a pinpoint that gets really hot, the device does the same thing with sound waves,” said Pejman Ghanouni, MD, PhD, a postdoctoral scholar in radiology.

The patient lies in a magnetic resonance imaging scanner that creates a three-dimensional image of the tumor and enables precise targeting of the lesion with ultrasound while avoiding normal tissues. The MRI scanner can also measure the temperature at the treatment site to ensure that there is a sufficient level of heating. Focused ultrasound is thought to work by destroying the nerves that line the bone containing the tumor, Ghanouni said.

Stanford is one of 17 sites around the world involved in the phase-3 trial. Ghanouni and interventional radiology professor David Hovsepian, MD, are the lead investigators of the trial at Stanford. The sponsor of the study is InSightec Inc., the company that makes the device and is headquartered in Haifa, Israel.

With advances in cancer detection and treatment, survival rates among

cancer patients have been improving. As a result, more cancer patients live long enough for the disease to spread to their bones. External-beam radiation therapy is the standard of care, and for many it provides adequate relief. However, 20 to 30 percent of patients treated with radiation therapy get little or no relief. While some may receive sufficient pain reduction with additional radiation treatment, others may not be eligible for more because it risks damaging their normal, surrounding tissues. For these patients, ExAblate, which uses ultrasound rather than ionizing radiation, could be a viable alternative.

Three phase-2 studies using the device, published in the Annals of Oncology, Radiology and the Annals of Surgical Oncology, provided evidence that the treatment could be beneficial. Of 46 patients in those studies who underwent the treatment and completed their follow-up visits, 39 reported a significant reduction of pain. Six patients had no response, and one reported worse pain. Patients who benefited from the treatment also reported reducing their use of narcotic pain relievers, according to the studies. (There were no control groups in these studies.)

To be eligible for the trial, patients must be at least age 18 and have pain due to cancer that has invaded their bones or from multiple myeloma, a type of cancer that occurs in the bone marrow. The trial participants will be randomized, meaning some patients will receive a placebo treatment and others the actual treatment. However, those who received the placebo have the option of getting the real treatment four weeks later.

In addition, Ghanouni and Hovsepian are running an early-stage (phase 1/2) trial using high-intensity, focused ultrasound waves in a slightly different version of the ExAblate device involving the same types of patients with the same types of cancer. There will be no placebo group for this trial.

Provided by Stanford University Medical Center