National research study to assess new treatment for painful vertebral fractures

October 28 2010

Physicians at The Medical College of Wisconsin are conducting the KAST clinical trial at Froedtert Hospital to assess the safety and effectiveness of a new vertebral augmentation treatment (Kiva) for painful vertebral compression fractures (VCFs) due to osteoporosis.

Sean Tutton, M.D, associate professor of radiology and surgery at the Medical College, is principal interventional radiology investigator for this multi-institutional, national trial. This prospective, randomized, controlled trial will compare outcomes of the investigational Kiva device using a coil implant with cement, to the current treatment, kyphoplasty using small orthopedic balloons and cement to repair painful fractures of the spine.

"The study will evaluate whether the Kiva procedure, using a more elastic implant and less cement placed strategically, will be equally safe and effective to kyphoplasty" says Dr. Tutton. It may also demonstrate that the more elastic implant and use of less cement will prove superior to kyphoplasty.

VCFs occur when a vertebra cracks, fractures, or collapses. These fractures are extremely painful and often debilitating. Over 700,000 osteoporosis-related vertebral compression fractures occur each year in the US alone. It is estimated that two-thirds of vertebral compression fractures are never diagnosed because many patients dismiss their back pain as a sign of aging and/or arthritis.

When bones become fragile and brittle from osteoporosis, everyday activities can trigger vertebral compression fractures. Bending to lift an object, missing a curb, or slipping on a wet surface can put the spine at risk of fracture. Multiple vertebral compression fractures significantly changes the structure and shape of the spine and can affect the internal organs and body functions, negatively impacting the overall health of the individual, daily activities, and quality of life.

The primary treatment for VCFs is typically conservative care consisting of bed rest, analgesics, and physical therapy. Interventional treatments for VCFs, include balloon kyphoplasty and vertebroplasty. These treatments aim to stabilize the fractures, providing earlier pain relief, and functional improvement.

Dr. Tutton pointed out that recent studies comparing vertebroplasty to sham procedures have resulted in confusion as they, on first glance, failed to demonstrate significant clinical improvement. When the trials are evaluated more critically, it is apparent that difficulties with patient selection and under-enrollment limited these trials' ability to prove their hypotheses. The prospective randomized FREE trial and recently published Vertos II trial (Lancet) both support the efficacy and safety of kyphoplasty and vertebroplasty. From the available data we know that patients who failed conservative care at four to six weeks and then received vertebroplasty or kyphoplasty experienced significant reduction in pain, earlier resumption of normal activities and most importantly preservation of independence.

Individuals eligible for the KAST study must have one or two osteoporotic spine fractures, be over age 50, and have been unsuccessfully treated by conservative care for at least 6 weeks.

The Kiva System, considered the next generation in the treatment for VCFs, is approved in Europe. The results of the current study will be

submitted to the FDA for potential clearance in the US.

Provided by Medical College of Wisconsin