



Arthritis News

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**Embargoed for Release at
6:15 PM ET, Sunday Oct. 17, 2004**

MEDICATION SHOWS PROMISING RESULTS IN REDUCING FRACTURE RISKS FOR OSTEOPOROSIS PATIENTS

SAN ANTONIO, TEXAS—Strontium ranelate, a new oral medication on the horizon, may reduce spinal, non-spinal, hip and other fractures in older women with osteoporosis, according to research presented this week at the American College of Rheumatology Annual Scientific Meeting in San Antonio, Texas.

In a large phase III program, post-menopausal women were randomly assigned strontium ranelate or a placebo, along with calcium and vitamin-D supplements for three years. The phase III testing was broken down into two multi-national, double blind controlled studies. One focused on the possible reduction of fractures of the spine in nearly 1,650 women, average age 69; the other studied non-spinal fractures in more than 5,000 women, average age 76. All women studied had low bone density.

In both studies, participants experienced a significant reduction in fracture risk. Over the three-year period, 36 percent fewer women 74 years of age or older suffered hip fractures. Concurrently, spinal and non-spinal fractures were reduced by 32 percent and 31 percent, respectively, in the subgroup of elderly women, ages 80 and older. Strontium ranelate appeared to both increase bone formation and decrease bone density loss in the majority of patients, demonstrating a good bone and general safety response.

Osteoporosis weakens bones, leaving them subject to fracture, primarily in those over the age of 50 and in one out of every two women. In the U.S. alone, some eight million women and two million men run the risk of fracture leading to chronic pain, long-term disability and even death from this silent disease. Based on the present data, strontium ranelate may become a potential treatment option for those patients with osteoporosis and at high risk for spinal and non-spinal fractures.

“Strontium ranelate is the first compound to simultaneously decrease bone resorption and stimulate bone formation,” said Jean Yves Reginster, MD, Dept of Public Health, Epidemiology and Health Economics, University of Liège, Belgium and World Health Organization Collaborating Center for Public Health Aspects of Rheumatic Diseases, who was an investigator in the study. “Given this and its outstanding safety profile, strontium ranelate could prove to be a first-line treatment option for women with low bone mineral density with or without prevalent fractures as well as for elderly women with increased risk factors of hip fractures.”

The American College of Rheumatology is the professional organization for rheumatologists and health professionals who share a dedication to healing, preventing disability and curing arthritis and related rheumatic and musculoskeletal diseases. For more information on the ACR’s annual meeting, see www.rheumatology.org/annual.

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Editor’s Notes: Dr. Reginster will present this research during a scientific session at the ACR Annual Scientific Meeting from 12:15–2:00 PM CT (1:15–3:00 PM ET) on Tuesday, October 19, in Exhibit Hall C–D of the Henry B. González Convention Center. He will be available for media questions during a briefing at 1:30 PM CT (2:30 PM ET) on Tuesday, October 19, in the on-site Press Conference Room, Room 218.

A New Treatment for the Reduction of Vertebral and Non-Vertebral Fractures in Post-Menopausal Women with Osteoporosis

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Strontium ranelate, has been reported to have a dual action on bone metabolism, simultaneously increasing bone formation and decreasing bone resorption. A large phase III program including 2 multinational, double blind, placebo controlled studies was performed. In both studies, patients were randomly assigned to strontium ranelate 2g/day or placebo for 3 years and calcium and vitamin-D supplementation.

The SOTI study (Spinal Osteoporosis Therapeutic Intervention) focused on the vertebral anti-fracture efficacy of strontium ranelate, in 1649 post menopausal women with osteoporosis [age: 69.7(7.3) years; Lumbar Bone Mineral Density (BMD T-score: -3.6(1.3); mean(SD),]. It has demonstrated the early and sustained vertebral anti-fracture efficacy of strontium ranelate in the intent-to-treat (ITT) population, with a relative risk (RR) reduction of vertebral fracture of 49% ($p < 0.001$) the first year of treatment and 41% ($p < 0.001$) over 3 years.

The TROPOS study (Treatment Of Peripheral Osteoporosis) investigated the efficacy of strontium ranelate on non-vertebral fractures in 5091 women with post-menopausal osteoporosis [age: 76.8(5) years, Femoral Neck BMD T-score -3.1(0.6)]. In the ITT population, there was a significant reduction in the risk of experiencing a new non-vertebral fracture over 3 years (RR=0.84 95%CI [0.702;0.995], $p=0.04$). A significant reduction of 36% was observed over 3 years in the RR of hip fracture (RR=0.64, 95%CI[0.412;0.997]; $p=0.046$) in a subset of patients with an increased risk of hip fracture ($n=1977$; age ≥ 74 years and femoral BMD T-score ≤ -3).

A predetermined analysis of the pooled data from the 2 phase III clinical trials (SOTI and TROPOS) demonstrated a significant reduction over 3 years in the RR of vertebral and non vertebral fracture, RRR= 32% ($p=0.013$) and 31% ($p=0.011$) respectively, in the subgroup of very elderly patients (aged 80 years or more , $n=1488$).

In both Phase III studies and in all the subsets studied, strontium ranelate had a good bone and general safety profile.

The present data show the efficacy of strontium ranelate in reducing the risk of vertebral and non vertebral fracture, including hip fractures, and place it as a promising new first-line oral treatment for postmenopausal osteoporosis.

Disclosure: J. Reginster, None; K. Brixen, None; G. Bianchi, None; J. Hensen, None; A. Balogh, None; R. Lorenc, None; J. Cannata, None; P. Fardellone, None.