UT News
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****Sodium fluoride (for treatment of osteoporosis) advances into Phase III clinical trials

DALLAS--A promising new drug for the treatment of osteoporosis, a crippling bone disease that is common among postmenopausal women, is now ready for clinical testing in a large number of patients.

The drug, a slow-release form of sodium fluoride, is entering Phase III of FDA clinical trials, according to Dr. Charles Y.C. Pak at The University of Texas Health Science Center at Dallas, developer of the drug.

Advancing to Phase III trials indicates that the drug has successfully passed through two stages of clinical testing, in which safety and effectiveness of the drug have been found by Pak's research group.

Now hundreds of patient volunteers with established osteoporosis are needed for the Phase III, multi-center trials. The purpose of this phase is to confirm the research findings from Pak's initial patient studies over the past five years.

Pak is director of the National Institutes of Health-sponsored General Clinical Research Center at the health science center and chief of the UTHSCD Mineral Metabolism Unit. Funding for the osteoporosis drug research is being provided by NIH grants with endorsement of the FDA.

Sodium fluoride is a compound used for years by dentists to strengthen teeth. It is also known for its ability to build bone. "But while there is ample evidence that sodium fluoride can make more bone and prevent or treat osteoporosis, a high prevalence of side effects has precluded its wide usage," says Pak.

Therefore, a slow-release form of sodium fluoride was developed to overcome harmful side effects, including gastrointestinal and rheumatic complications.

In the drug tests, sodium fluoride will be administered with a calcium supplement, calcium citrate, also developed by Pak's group. Calcium citrate, shown in clinical studies to be much better absorbed through the walls of the intestine than the widely used calcium supplement, calcium carbonate, will be assessed for its effectiveness in preventing and treating osteoporosis.

Osteoporosis patients with early or advanced disease who wish to participate in the drug trials may do so by contacting one of the following participating medical centers. These centers belong to the Dallas Osteoporosis Study and Management Group organized by Pak two years ago. Each of these centers is equipped with a sophisticated device called a dual photon densitometer to determine bone density. Each will provide monitoring of patients throughout the trial.

The group is also interested in studying the affect of calcium supplements in the prevention of bone loss in early postmenopausal women so that fractures may be avoided. In this NIH-supported study, calcium supplements to be studied are calcium citrate and calcium carbonate.

(More)

Centers participating in the clinical trials include:
--AMI Medical Arts Hospital's Dallas Osteoporosis Centre
Dr. Sydney Lou Bonnick
630-3465
--Medical City of Dallas' Osteoporosis Care Center
Dr. Richard Berger
661-7512
--Methodist Medical Center's Osteoporosis Center
Dr. William Fears
942-2663
--Scott and White Clinic, Division of Endocrinology
Dr. Veronica Pieziak
817/774-3908
--Texas College of Osteopathic Medicine, Department of Medicine
Dr. Bernard Rubin
817/735-2332
--UT at Tyler
Dr. Joyce Ballard, Dr. Helen Graham
214/566-1471, ext. 323
--UTHSCD Aston Ambulatory Care Center's Osteoporosis Clinic (by referral only)
Dr. Khashayar Sakhaee and Dr. Jean Harvey
Please call Roy Peterson, R.N., for appointment
688-3745

After Phase III testing is complete, the medication may be approved by the FDA as a prescription drug in the treatment of patients with osteoporosis.

Pak and his UTHSCD team have developed several drugs for the treatment of calcium metabolism-related disorders. The researchers developed two FDA-approved drugs for the treatment of kidney stone-forming disorders. Two other kidney stone drugs are now under investigation. They have also developed and tested the calcium supplement, calcium citrate, for treating osteoporosis while lowering the risk of kidney stones.

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NOTE: The University of Texas Health Science Center at Dallas comprises Southwestern Medical School, Southwestern Graduate School of Biomedical Sciences and the School of Allied Health Sciences.