

# NEWS

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\*\*\*New drug for preventing kidney stones was released July 19 by FDA.

EDITORS' NOTE--The orphan drug "potassium citrate" was released today, July 19, by the FDA for use in preventing a common kidney stone-forming disorder called hypocitraturia.

Hypocitraturia is a condition in which a person has a low level of citrate in the urine, allowing for crystallization of stone-forming calcium salts. The disorder affects about 50 percent of all people needing medical treatment for active kidney stone disease--approximately 150,000 patients in the U.S.

Potassium citrate, a component of citrus fruits, was developed for use in kidney stone treatment by Dr. Charles Y.C. Pak of The University of Texas Health Science Center at Dallas. Research was funded by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. The Food and Drug Administration provided critical support by identifying needed studies.

Pak is professor of Internal Medicine at the health science center and director of the NIH-supported General Clinical Research Center here.

The drug represents the second of two orphan drugs developed and selectively used by Pak's group for kidney stone prevention. The other drug, sodium cellulose phosphate, was found effective in treating absorptive hypercalciuria, a stone-forming disorder frequently associated with increased absorption of calcium from food. The Mission Pharmacal Co. in San Antonio, which introduced sodium cellulose phosphate into the marketplace two years ago, will also market potassium citrate.

Three articles written by Pak and his associates on the effectiveness of potassium citrate appear in July issue of the Journal of Urology. Another article is slated to appear in the September issue of The American Journal of Medicine.

A long-term clinical trial of potassium citrate examined 89 of Pak's patients over a period of one to 4 years. In this overall group, which included patients with severe stone disease, results showed that individual stone formation declined in 97.8 percent of patients, remission was obtained in 79.8 percent and need for surgery for newly formed stones was eliminated. When results of 45 patients with less severe stone disease (one or less stones formed a year) were taken, treatment eliminated stone formation in 96 percent of patients. In patients who relapsed on other therapies, such as thiazide, the addition of potassium citrate brought clinical improvement.

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DALLAS--Medical treatment for preventing kidney stones must not be overlooked amidst excitement over technological and surgical advances in stone removal, says Dr. Charles Y.C. Pak of The University of Texas Health Science Center at Dallas.

Pak is professor of Internal Medicine at the health science

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add one--kidney stone drug

center and director of the National Institutes of Health-supported General Clinical Research Center here.

New and improved techniques for kidney stone removal--"blasting" stones with ultrasonic shock waves or pulling stones out through the patient's side through a small incision--can help patients avoid extensive surgery.

"But while this refined technology of stone removal is important, it would not be wise to ignore drug treatment to prevent repeated stone formation," says Pak.

Pak developed two orphan drugs for the prevention of kidney stones, including potassium citrate, which was approved for use today, July 19, by the FDA.

Studies show that more than 90 percent of patients with kidney stones have an underlying metabolic abnormality, says Pak. He and his group have identified a dozen of these metabolic causes and have devised selective treatment for each.

A group of 103 kidney stone patients, treated medically for over a year by the health science center team, was randomly selected for a study appearing this month in the Journal of Urology. The journal article was authored by Pak and his colleagues, Drs. Paul Peters and Glenn Preminger. The patients were divided into two groups. Fifty-two of the patients had existing stones and 51 patients were without evidence of stones within their kidneys.

Within the group with existing stones, new stone formation was completely arrested in 77 percent of the patients and a reduced stone formation rate occurred in 98 percent. In a group of 51 patients without existing stones, a similar remission (78 percent) and reduced stone formation rate (94 percent) was observed.

Cost effectiveness is a major benefit of medical therapy, the study points out. This is particularly true in patients with recurring kidney stone formation.

Removal of stones by blasting or excision, costs approximately \$6,000 to \$10,000 per surgery. In contrast, one can medically treat and follow stone patients for less than \$1,000 per year, says Pak.

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