

NEWS

The University of Texas Health Science Center at Dallas
5323 Harry Hines Boulevard Dallas, Texas 75235 (214)688-3404

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CONTACT: Susan Rutherford
OFFICE: 214/688-3404
HOME: 214/349-7820

*****New kidney stone drug
to be announced at press conference.

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Not for release until 1:30 p.m., May 24, 1984.

*****NOTE TO NEWS MEDIA: A press conference will be held May 24, 12:30 p.m. CDT, at The University of Texas Health Science Center at Dallas (room El.403), when kidney stone expert Dr. Charles Pak will announce a new orphan drug for the prevention of kidney stones. The press conference is sponsored jointly by the National Institutes of Health, Division of Research Resources and UTHSCD.

DALLAS--Kidney stone expert Dr. Charles Y.C. Pak today (May 24) will announce the development of a new drug, potassium citrate--a component of citrus fruits--for the prevention of certain calcium-containing kidney stones. Potassium citrate has been found effective in reducing the rate of stone formation or ceasing stone production in patients with "hypocitraturia", a condition in which a person has a low urinary citrate level.

Pak says hypocitraturia affects about 50 percent of all people requiring medical treatment for active kidney stone disease. These patients, numbering up to 200,000, can benefit from potassium citrate, he says. Pak is professor of Internal Medicine at The University of Texas Health Science Center at Dallas and director of the UTHSCD General Clinical Research Center, one of 74 such human research facilities funded by the Division of Research Resources, National Institutes of Health, at academic medical centers throughout the United States.

Potassium citrate was tested at the UTHSCD General Clinical Research Center in 78 patients with hypocitraturia. The research was funded by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. FDA approval is expected shortly.

Stones formed by patients involved in the research were composed of calcium oxalate or calcium phosphate (calcium stones make up the majority of kidney stones). Of the 78 patients, 74 percent stopped forming stones while on drug therapy and 96 percent had a reduced rate of stone formation. When treatment ended, the rate of stone formation jumped to an elevated level again.

Moreover, this treatment has virtually eliminated the need for surgery of new stones in these patients. These 78 patients underwent 56 surgeries during three years prior to initiation of treatment. Following treatment with potassium citrate (mean period of 1.8 years) only 9 surgeries were required, all for pre-existing stones and none for new stones. In patients who had small stones to begin with, some have shown a reduced stone mass.

Citrate, a substance normally found in urine, is an "inhibitor" of stone formation since it is capable of preventing the crystallization of stone-forming calcium salts, says Pak. Patients with hypocitraturia are therefore more prone to form calcium stones. In such persons, potassium citrate increases urinary citrate and therefore significantly reduces stone formation.

Hypocitraturia is the sole abnormality in some patients with stones while in others it may co-exist with other abnormalities, such as hypercalciuria (high urinary calcium). Therefore, potassium citrate can be used alone or in combination with other drug treatments. Causes of hypocitraturia are many and include: renal tubular acidosis (defective elimination of acid by the kidneys), chronic diarrheal problems and high animal protein intake.

(more)

add one, kidney stone drug

Hypocitraturia may also develop in patients taking thiazide, a drug commonly used to treat patients who form calcium stones due to hypercalciuria. Some patients taking thiazide may continue to form calcium stones because of the low urinary citrate.

Pak and his colleagues studied 14 patients who relapsed (continued to form stones) on thiazide. When potassium citrate was added, these patients ceased to form stones or developed stones less frequently. Therefore, "potassium citrate may be an ideal potassium supplement for patients taking thiazide for calcium stones," says Pak.

Potassium citrate is the second drug developed by Pak's group. The orphan drug "sodium cellulose phosphate" or SCP, was approved by the FDA in December 1982 after 15 years of testing by Pak's group. SCP was found clinically effective in the treatment of "absorptive hypercalciuria," a stone-forming disorder frequently associated with increased absorption of calcium from food.

The development of both drugs by Pak, potassium citrate and sodium cellulose phosphate, was made possible by grants from the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases. The FDA has guided Pak's group in defining necessary studies.

SCP and potassium citrate would both be considered orphan drugs because their compositions are basic and well-known. Moreover, it is not commercially attractive to produce these drugs because of relatively few persons in whom they could be used. Potassium citrate, for example, is a component of orange juice. "It is naturally occurring and has been on the market for many years as an alkalinizing agent and as a potassium supplement," says Pak.

So why not just drink orange juice to prevent kidney stones?

"To provide enough potassium citrate a person would have to drink one quart a day, which many people could not tolerate. Also, orange juice contains calcium and sugar. Both components may raise urinary calcium. Then there is the high cost and sometimes unwanted calories," Pak says.

An inexpensive form of potassium citrate is being made into a slow release pill under the name Urocit by Mission Pharmacal Co. in San Antonio.

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