

Cystone for the Treatment of Cystinuria

Doctors at the Mayo Clinic are working with investigators at The Himalaya Drug Company to test a drug for the treatment of cystine kidney stones and are looking for qualifying participants. The aim of the research study is to discover if this drug has the potential to decrease formation of kidney stones and possibly even dissolve existing ones.

Men or women 21 years of age and older that have been diagnosed with cystine kidney stones and have at least one kidney stone present at this time, may be eligible for this research study. Pregnant or breast feeding mothers are not presently being accepted.

Participants in this study will continue their current cystine stone prevention program. They will be seen by a Mayo Stone Clinic physician and have a baseline CT scan of their kidneys, blood, and two 24-hour urine collections. Participants will then be given an herbal medication currently available over-the-counter called Cystone, two tablets two times daily by mouth, or an identical placebo for six weeks. At the end of the six weeks, two more 24-hour urine samples will be collected. These can be returned in person or mailed in. Then the participants who were getting Cystone will receive a placebo for another six weeks and the participants who were getting a placebo will receive Cystone for another six weeks. No one will know until the end of the study in which order you receive the Cystone and placebo. At the end of the second six-week period, two more 24-hour urine samples are collected and returned in person or by mail. Then all participants take Cystone for an additional 46 weeks. At the end of this time, a concluding CT scan, blood work, urine collection, and physician visit occur.

In summary, this is a 59-week trial requiring two visits to Mayo Clinic during which you are guaranteed to receive the research medication, Cystone, for 52 weeks. There is no cost for the Cystone or the 24-hour urine samples in the middle of the study. The evaluation and testing at the beginning and end of the study are considered standard kidney stone treatment and must be paid for by you or your health insurance. No travel expenses or remuneration is offered from this study. Cystone has been shown in previous studies to be extremely safe and free of side effects.

What is a CT scan?

A CT (computed tomography), sometimes called a "CAT scan", is a specialized imaging procedure performed to obtain detailed images of the inside of your body using x-rays. For this study, the exam will be limited to the kidneys in order to determine if you have kidney stones. No intravenous and no oral contrast material is needed for this type of CT exam and the average time needed for you to be positioned on the CT imaging table is typically less than 10 minutes. If stones are present, this specialized, quantitative CT exam will also be able to calculate the kidney stone burden by confirming the size, number and location of the stones in your kidneys. The CT scan is obtained using carefully focused x-rays which are set at the lowest possible radiation dose precisely tailored to your body. A technologist with special training in CT imaging will acquire your images. During the exam you will be asked to hold your breath for approximately 10-15 seconds in order to obtain the CT study without any motion. A physician radiologist with expertise in looking at kidney stones will review your images and report these findings to your doctor.

Some costs that you may need to know for yourself or for your insurance company:

CT (quantitative) \$885

Interpretation \$870

Stone Clinic Physician Consultation \$390

pH, Urine 24 hour \$26.50

Sodium 24 hour \$34.50

Cystine 24 hour \$345

For accommodations, we suggest this web site:

<http://mayoclinic.org/travel-rst/lodging.html>

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