

Interstitial cystitis (IC) is a disabling condition affecting women and men of all ages and ethnic origins. The symptoms vary but usually include bladder or pelvic discomfort and/or pain, urinary urgency, and urinary frequency that are not relieved by antibiotics. The cause of IC is unknown, and there are no standard treatment guidelines.

### **The Interstitial Cystitis Clinical Trials Group**

The ICCTG is studying all aspects of IC with the hope of finding effective treatments.

Eight clinical centers are participating in the ICCTG. A Data Coordinating Center (DCC) is managing study activities and collecting and analyzing information gathered from patients.

The National Institute of Diabetes and Digestive, and Kidney Diseases of the National Institutes of Health is funding the study.

### **Who is Eligible?**

Doctors seek people who have been diagnosed with interstitial cystitis. Potential study participants will be asked to have blood drawn for lab studies and complete questionnaires. Some conditions, such as neurologic disease, and some prior treatments or surgeries may exclude some people from participating in the study.

### **What is Involved?**

The study requires:

- ◆ Urine specimen(s)
- ◆ Medical history and physical exam(s)
- ◆ Voiding Diary(ies)
- ◆ Symptom Questionnaires

Each procedure and piece of information provides a stepping stone in the path to understanding interstitial cystitis.

*Information about individual patients is held in strict confidence.*

This study will evaluate the effectiveness of two oral drugs: Elmiron

and hydroxyzine, given either alone or in combination, and compared with no treatment. Study participants will be randomly assigned to one of four groups: Elmiron alone, hydroxyzine alone, both Elmiron and hydroxyzine, or placebo.

Patients will come into the clinic to answer questions about symptoms every seven weeks for 24 weeks. There will be phone contact in between clinic visits. Participants will be seen by doctors, research nurses during regular office visits.

**For More Information :**

**Contact the medical center identified  
in the box below or:**

**Lori Ann Smith  
ICCTG Project Manager  
University of Pennsylvania  
Fax (215) 573-6262**

**\*Ask your nurse for the names of other doctors  
who are seeing ICCTG Study patients at this  
center.**

**To make an appointment, contact:**

**INTERSTITIAL CYSTITIS  
CLINICAL  
TRIALS  
GROUP**

**ICCTG STUDY #1**

**Elmiron and Hydroxyzine  
for the Treatment of  
Interstitial Cystitis**

**INFORMATION FOR  
PATIENTS**

*A study funded by the  
National Institutes of Health*

