



OCTOBER 2006

# PROSTATITIS INFORMATION

The Prostatitis Foundation, 1063 30th Street, Smithshire, Illinois 61478 • Fax 309-325-7184  
FREE INFORMATION PACKET — TOLL FREE: 888-891-4200

To chronic and short term prostatitis patients.

We want to inform each of you about the clinical trials available now. The research centers need a steady flow of new patients to complete this research to determine the cause and cure for prostatitis. There is an urgent need for this research, which will enable researchers to weed out false leads and explore hopeful possibilities.

The Prostatitis Foundation has asked Congress for funds, which enable the NIH (National Institute of Health) to fund this research. These researchers want to enroll prostatitis patients to complete these clinical trials. You can contact one of these centers to see if you are eligible.

University of Washington-Harborview Medical Center  
Seattle, Washington  
John N. Krieger, M.D., Principal Investigator  
Contact: Susan O. Ross, RN, (206) 543-3898  
or Leslie Butler (206) 616-7416

Temple University School of Medicine  
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The University of Mississippi Medical Center  
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Contact: Darlene Marko RN, BSN, CCRC (312) 695-3898

Cleveland Clinic  
Cleveland, Ohio  
Daniel Shoskes, M.D., Principal Investigator  
Contact: Donel Murphy, RN (216) 445-7505

Queen's University  
Kingston, Ontario, Canada  
J. Curtis Nickel, M.D., Principal Investigator  
Contact: Joe Downey, M.Sc., CCRP (613) 548-7832  
or Janet Clark-Pereira ACT, CCRP (613) 548-7805

Stanford University Medical Center  
Stanford, California  
Rodney Anderson, M.D., Principal Investigator  
Contact: Christine Chan, M.D., (650) 498-4240

David Geffen School of Medicine at UCLA  
Los Angeles, CA  
Mark S. Litwin, MD, MPH, Principal Investigator  
Contact: Gwendolyn Byrd, MA (310) 267-2526

Charles R. Drew University  
Los Angeles, CA  
Nand S. Datta, MD, Co-Investigator  
Contact: Kawajalen Mervin (310) 668-4545

## An Introduction to Clinical Trials

Choosing to participate in a clinical trial is an important personal decision. The following frequently asked questions provide detailed information about clinical trials. In addition, it is often helpful to talk to a physician, family members, or friends about deciding to join a trial. After identifying some trial options, the next step is to contact the study research staff and ask questions about specific trials.

### What is a clinical trial?

A clinical trial (also clinical research) is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. Interventional trials determine whether experimental treatments or new ways of using known therapies are safe and effective under controlled environments. Observational trials address health issues in large groups of people or populations in natural settings.

### Why participate in a clinical trial?

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

For full text see [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

## PROSTATITIS TAKES CENTER STAGE AT THE 2006 AMERICAN UROLOGICAL ASSOCIATION MEETING

A sign that interest is high and research is progressing on chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) was a plenary session lecture devoted entirely to the topic. For a large audience, J. Curtis Nickel, MD, from Queen's University, in Kingston, Ontario, detailed how the research is evolving and what today's best treatments are.

Thanks in large part to NIH sponsorship, there has been a "literal tsunami" of research on CP/CPPS in the last 5 years, said Dr. Nickel. The literature includes 11 randomized, placebo controlled trials, and in those, many treatments have performed well, but so have placebos. A better measure of what therapies might be effective, he said, is a

difference in improvement between treatment and placebo, called "treatment effect," that is at least 4 to 6 points on the NIH Chronic Prostatitis Symptom Index (NIH-CPSI). Alpha blockers have passed that threshold. So have mepartricin and quercetin, but in small, single center trials. Saw palmetto and the rye-pollen extract Cernilton, which was tested in a study presented at this meeting, need a closer look, he said.

Antibiotics don't work in heavily pretreated men with longstanding disease, and anti-inflammatories simply don't work, said Dr. Nickel. He suggested that urologists could still try antibiotics, but only early in the disease and for not more than 4 weeks.

He urged urologists to catch and treat the problem early, since research implies that various damaging events, from infection to trauma, can start the CP/CPPS process, and if that damage isn't resolved or controlled quickly, pain can become centralized in the nervous system.

After trying alpha blockers for a minimum of 12 weeks, urologists could try adding anti-inflammatories; herbal therapies; tricyclic antidepressants, such as amitriptyline (Elavil); gabapentinoids, such as gabapentin (Neurontin) and pregabalin (Lyrica); and muscle relaxants, such as cyclobenzaprine (Flexeril), diazepam (Valium), or baclofen (Lioresal), he said. For patients who have interstitial cystitis-like symptoms—urinary symptoms and pain in the area of the bladder—pentosan polysulfate (Elmiron) might help. Then, if patients still don't do well, he urged his colleagues to "think outside the box" and try physical therapy and cognitive behavioral therapy.

New thinking is emerging in the CP/CPPS research community that is getting away from focusing on the prostate alone and is including the organs around it—the bladder, muscles, ligaments, joints, and nerves—as well as the central nervous system. Future research by the Chronic Prostatitis Collaborative Research Network (CPCRN) will be focused on these new ideas, testing treatments including pregabalin (Lyrica) and alpha blockers in early disease, physical therapy, and cognitive behavioral therapy.

In specialty sessions at the meeting, investigators presented some 20 research studies. Among the treatments studied were physical therapy and relaxation, injections of botulinum toxin A (Botox) into the prostate and pelvic floor, the rye-pollen extract Cernilton, and an alpha blocker. Stanford

researchers using the physical and relaxation therapy presented their results last year on the overall effects of therapy, and this year, they demonstrated that the therapy can also improve sexual function. The therapy doesn't work for every man with severe CP/CPPS, but when it does, the decrease in sexual dysfunction can be substantial. Cernilton has become a popular herbal remedy, but results have been equivocal in benign prostatic hyperplasia (BPH or prostate enlargement). In the study presented here, although the effects on urinary symptoms were not significant, the effects on pain and quality of life were. Based on a preliminary study presented here, Botox seems to have the most promise for controlling pain and also for frequency. Similar to previous studies, improvements with an alpha blocker were modest.

Studies on cost, prevalence, and risk factors were revealing and even controversial. Direct medical costs for men who have CP/CPPS are about a quarter more to double the costs for other men, highlighting the need for more effective therapy. In a study of CP/CPPS in African American men, the prevalence of diagnosed prostatitis was 7%. Odds of having prostatitis were higher in men who had had moderate to severe lower urinary tract symptoms and lower in men who were physically active.

Potentially controversial was an analysis of the Boston Area Community Health Survey indicating that men who had CP/CPPS symptoms were two to three times more likely to have been abused as children or adults than other men. How abuse might play into CP/CPPS is unclear. Evidence of the trend to look at the socioeconomic effects of CP/CPPS was a study that showed female partners of patients suffered more depression and had poorer physical and mental health overall than other women. The cause or causes of CP/CPPS are still speculative, but there's more evidence for dysfunction in the "fight or flight" neural-hormonal systems of the body. The idea that CP/CPPS is an inflammation of the prostate gland took a blow from an analysis of prostate samples and rates of CP/CPPS in men who were participating in a large trial of a treatment for BPH.

These and all the other studies related to CP/CPPS and prostate inflammation presented at the 2006 AUA Annual Meeting are summarized at [www.prostatitis.org](http://www.prostatitis.org)

Supporters of our website are Farr Labs, LLC the makers of ProstaQ for chronic prostatitis. For more information visit [ProstaQ.com](http://ProstaQ.com) or call 1-877-284-3976

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