UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE
Clinical Research Computing Unit (CRCU)
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CPCRN-2 RCT #1(ALFUZOSIN TRIAL) PROTOCOL AMENDMENT #2

Introduction:

The Chronic Prostatitis Collaborative Research Network 2 (CPCRN-2) Clinical Trial Protocol #1 entitled: "A Randomized Multicenter Double-Blind Clinical Trial to Evaluate the Efficacy and Safety of 10mg Alfuzosin in the Treatment of Chronic Prostatitis / Chronic Pelvic Pain Syndrome (CP/CPPS) in Recently-Diagnosed and/or Newly-Symptomatic Alpha-blocker Naïve Patients"- Version 1.0 – Effective August 16, 2004, was developed by the CPCRN-2, and will be maintained by the Data Coordinating Center (DCC) at the University of Pennsylvania over the course of the study through issuance of protocol amendments and revisions.

The first edition of this protocol (Version 1.0, August 16, 2004) is being amended as of the effective date July 20, 2005. Please refer to the protocol table of contents for the location of changes listed below.

Summary of Protocol Amendment #2

1. Revise entry criteria to remove "chronic" epididymitis from the list of symptoms in Deferral Criteria #4 and to remove Deferral Criteria #6 to reflect a label change allowing the use of erectile dysfunction medications with alpha blockers.

2. Allow prospective participants to return for their Screening Visit #2 when their 2-day urine culture results (required to assess eligibility) are available, rather than wait at least 7 days to return.

1. PARTICIPANT CRITERIA

a. [Section 4.1.3 Deferral Criteria #4] Participant has experienced symptoms of acute or chronic epididymitis within the past three (3) months.

- ***Change Protocol Text to Read*:** Participant has experienced symptoms of acute epididymitis within the past three (3) months.

b. [Section 4.1.3 Deferral Criteria #6] Participant has been taking excluded medications such as Cialis®, Levitra®, and Viagra® in the past one (1) week.

- ***Remove this deferral criteria***

2. TRIAL TESTS AND PROCEDURES

a. [Section 7.1 Procedural Summary- second paragraph] This study is comprised of phases for each participant: i) the screening phase and ii) the treatment and follow-up phase. The screening phase, which assesses a participant's eligibility via inclusion, exclusion, and

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deferral criteria, will consist of two baseline visits no more than four (4) weeks and no less than one (1) week apart.

- ***Change Protocol Text to Read*:** This study is comprised of phases for each participant: i) the screening phase and ii) the treatment and follow-up phase. The screening phase, which assesses a participant's eligibility via inclusion, exclusion, and deferral criteria, will consist of two baseline visits no more than four (4) weeks and no less than two (2) days apart (when 2-day urine culture results are available).

b. [Section 7.2 Screening Visit#1 – first sentence] The first screening visit should occur no more than four (4) weeks and no less than one (1) week prior to randomization.

- ***Change Protocol Text to Read*:** The first screening visit should occur no more than four (4) weeks and no less than two (2) days prior (when 2-day urine culture results are available) to randomization.

c. [Section 7.3 Screening Visit#2 – first sentence] Screening Visit #2 should be completed at least one (1) week after, but no more than four (4) weeks after Screening Visit #1.

- ***Change Protocol Text to Read*:** Screening Visit #2 should be completed at least two (2) days after (when 2-day urine culture results are available), but no more than four (4) weeks after Screening Visit #1.