CPCRN-2 RCT #1(ALFUZOSIN TRIAL) PROTOCOL AMENDMENT

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 April 12, 2005. Please refer to the protocol table of contents for the location of changes listed below.

Summary of Protocol Amendment #1

The goals of this amendment are:

1) To update Clinical Site name changes
2) To allow a physical examination completed by the Principal Investigator or his/her designee on a newly diagnosed study participant prior to the participant signing study consent to be utilized as the physical examination currently required at study baseline screening visit 1. This physical examination and associated urine and/or EPS lab results, conducted up to four (4) weeks prior to study baseline screening visit #1, will be acceptable for satisfying screening visit requirements. A focused physical examination is part of the routine standard of care in the initial evaluation of a urology patient and therefore, will reduce participant burden and inconvenience in not having multiple identical procedures performed within a short period of time.
3) To clarify that all sites do not need to use the same brand of dipstick for urinalysis.
4) To clarify sample size adjustments and the frequency of Patient Recruitment reports.

1. STUDY DESIGN AND OBJECTIVES

[Section 2.5 Study Organizations]

- "Cleveland Clinic, Florida" changed to "Cleveland Clinic, Ohio"
- "University of Washington" (Berger site) changed to "University of Washington Medical Center/Harborview Medical Center/UW Medicine"

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- "University of Washington-Harborview Medical Center/University of Sciences Malaysia" (Krieger site) changed to "University of Washington/University of Sciences Malaysia"

2. TRIAL TESTS AND PROCEDURES

- ***Current Protocol Text Reads:***

[Section 7.2 Screening Visit#1 – item #6] *Physical Examination*. Each participant will undergo a focused physical examination. This examination will include an abdominal exam, external genital exam, rectal exam, prostate exam, and perineal exam.

***Change Protocol Text to Read*:**

[Section 7.2 Screening Visit#1 – item #6] *Physical Examination*. Each participant will undergo a focused physical examination at this baseline visit. This examination will include an abdominal exam, external genital exam, rectal exam, prostate exam, and perineal exam. If the participant has received a prior focused physical examination conducted by the Principal Investigator or his/her designee within four (4) weeks of study enrollment, a documented copy of this prior physical examination will be acceptable.

- ***Current Protocol Text Reads:***

[Section 7.2 Screening Visit#1 – item #7] *Urinalysis, Urine, and EPS Specimens for Microscopy and Culture.* Each participant will provide two (2) urine specimens (VB2 and VB3) and an EPS (expressed prostatic secretion) specimen for either analysis or culture.

***Change Protocol Text to Read*:**

[Section 7.2 Screening Visit#1 – item #7] *Urinalysis, Urine, and EPS Specimens for Microscopy and Culture.* Each participant will provide a VB2 specimen, a VB3 and/or EPS (expressed prostatic secretion) specimen for either analysis or culture. If the participant has provided these specimens as part of the focused physical examination conducted by the Principal Investigator or his/her designee within four (4) weeks of study enrollment, a documented copy of these laboratory results will be acceptable.

- ***Current Protocol Text Reads:***

[Section 7.2 Screening Visit#1 – item #7] *Urinalysis, Urine, and EPS Specimens for Microscopy and Culture.* Dipstick urinalysis will be conducted on the midstream urine (VB2) for macroscopic analysis; all centers will be required to use the same brand of dipstick.

The statement "all centers will be required to use the same brand of dipstick" has been removed.

3. STATISTICAL CONSIDERATIONS

- ***Current Protocol Text Reads:***

[Section 10.2 Sample Size Calculations] "This proposed sample size includes adjustments for clustering within clinical sites (5% increase), withdrawal (15% increase), and interim monitoring (5% increase)"

***Change Protocol Text to Read*:**
[Section 10.2 Sample Size Calculations] "This proposed sample size includes adjustments for clustering within clinical sites (20% increase) and interim monitoring (5% increase)".

- **[Section 10.6 Report Table]**

Frequency of Patient Recruitment/Targets Report changed from "q2 weeks" to "q4 weeks".