Chronic Prostatitis Collaborative Research Network 2 (CPCRN2) - Alfuzosin Study

This study was conducted as part of the second Chronic Prostatitis Collaborative Research Network (CPCRN2). The archive contains the study protocol and related descriptive documentation; study forms; and data collected by the study.

The archive is organized in five directories:

1. Documentation
2. Forms
3. Data
4. Overview and Publications
5. DSIC (Dataset Integrity Check)

The archive also contains a study Roadmap document that describes the content of the archive.

1. Documentation

The Documentation directory contains documentation of the Alfuzosin protocol and descriptive documentation, including:

- **MOP**: a subdirectory containing the Manual of Procedures(MOP)
  - MOP_020805_Version1.0.pdf: the manual for data collection
- **Protocol**: a subdirectory containing the following three files:
  - Alfuzosin trial_Protocol Version 2.0_091205.withAmendments.pdf- the Alfuzosin study protocol including amendments
  - Alfuzosin trial_Protocol amendment1_052305.pdf- the first Alfuzosin study protocol amendment
  - Alfuzosin trial_Protocol amendment2_080305.pdf- the second Alfuzosin study protocol amendment

2. Forms

The Forms directory holds a single PDF file that contains all 23 of the forms used in the study although the forms in the PDF are in no specific order. The 23 forms used during data collection, include forms used to collect actual data for analysis and forms that were administrative, used to manage the study. In the table below, administrative forms are categorized separately from data forms. The forms are described in Table 1.

Table 1: Study Forms

Form Code	Form Name	Visit Completed	Completed By	Purpose
Administrative Forms				
AE Legend	Adverse Events and Serious Adverse Events – Legend	NA	NA	Code list of adverse events
PRESCR	Pre-screening Summary *	NA	RC	Monthly reporting form
***** Not a PID specific form, used prior to subject enrollment				
Data Forms				
CPSI	NIH – Chronic Prostatitis Symptom Index (standardized)	1,2,3,4	Self admin	Measure of symptoms
DEMO	Demographics	1	Self admin	Characteristics of subject
DISP	Dispensing Log	2,3	RC	Notation of drugs given to subject
DCOMP	Drug Compliance	3,4	RC	Notation of quantity of drugs taken by subject
ELIG	Eligibility Checklist	1,2	RC	Confirms study criteria
EUT	EPS and Urine Testing	1	RC	Lab report of urine sample
AE	Events and Serious Adverse Events	2,3,4	RC	Reports adverse events during study
HADS	Hospital Anxiety and Depression Scale©	2,3,4	Self admin	Measure of anxiety levels
IIEF	International Index of Erectile Function®	2,3,4	Self admin	Measure of sexual function
MSHQ	Male Sexual Health Questionnaire	2,3,4	Self admin	Measure of sexual behaviors
MEDHX	Medical History	1	RC + subject	Medical record abstract
MCGILL	McGill Pain Questionnaire® (MPQ)	2,3,4	RC + subject	Measure of pain levels
EXP	Participant Expectations Questionnaire	2	Self admin	Report of subject attitude toward study participation
EXAM	Physical Exam	1	RC	Medical record abstract for visit
RAND	Randomization	2	RC	Confirms eligibility/assigns subject to drug/placebo
SF12	SF12 – Health Status Questionnaire®	2,3,4	Self admin	Measure of current health
SSTOP	Study Stop Point	4 or earlier	RC/PI	Information related to subject termination form study
SYM	Symptom Assessment	1,2,3,4	Self admin	Rating scale for specific symptoms
TSTOP	Treatment Stop Point	4 or earlier	RC	Information related to subject termination of treatment
UNMASK	Unmasking Record	SAE and/or PI discretion	RC/PI	Information on unmasking of study product assigned
URINE	Urine Screening	1	RC	Pre-randomization dipstick analysis of urine

3. Data

The Data folder contains two subcategories. The folder called Analysis Files and Results contains analysis and program files used for study publications. The subdirectory called Raw Data contains SAS data files of the study data forms.

3.1 Raw Data- subdirectory contains 19 SAS data files of data that correspond to the study data forms. The forms used to collect study data, with their associated SAS data files (if applicable) are described in Table 2.

Table 2: Study Data Forms with Associated Files

#	Data file	Study Form	Description	Record Count
1	ae.sas7bdat	AE	Listing of all visits, visit dates and occurrence of adverse events for 39 subjects	751
2	aelog.sas7bdat	AE	Listing of adverse events only-contents of Adverse Events Form	265
3	cpsi.sas7bdat	CPSI	NIH – Chronic Prostatitis Symptom Index; forms contents for all visits; all subjects	1016
4	demo.sas7bdat	DEMO	Demographic data for 39 subjects	272
5	disp.sas7bdat	DISP	Dispensing Log; drugs given; visits 2/3 to 30 subjects	505
6	dcomp.sas7bdat	DCOMP	Drug Compliance Log; record of drugs used; visits 3/4; compliance rate	477
7	eut.sas7bdat	EUT	EPS and Urine Testing	271
8	hads.sas7bdat	HADS	Hospital Anxiety and Depression Scale©	742
9	iief.sas7bdat	IIEF	International Index of Erectile Function®	741
10	mshq.sas7bdat	MSHQ	Male Sexual Health Questionnaire	731
11	medhx.sas7bdat	MEDHX	Medical History	272
12	mcgill.sas7bdat	MCGILL	McGill Pain Questionnaire® (MPQ)	736
13	exp.sas7bdat	EXP	Participant Expectations Questionnaire	270
14	rand.sas7bdat	RAND	Randomization (random_arm =620 records)	272
15	random_arm.sas7bdat	No form	Tracking of ARM study subject assigned (A/B)	620
16	sf12.sas7bdat	SF12	SF12 – Health Status Questionnaire®	743
17	sstop.sas7bdat	SSTOP	Study Stop Point	272
18	sym.sas7bdat	SYM	Symptom Assessment	1010
19	tstop.sas7bdat	TSTOP	Treatment Stop Point	272

3.2 Analysis Files and Results -- this subdirectory contains 14 SAS and STATA program, dataset, and output files.

The following files were used in the analysis of the primary manuscript to document: 1) analyses conducted for the manuscript, 2) calculation of study center-adjusted 95% CIs for differences in the CPSI primary endpoint by treatment, and 3) calculation of study-center adjusted 95% CIs for the GRA response measure (as published in the article entitled **Alfuzosin and symptoms of chronic prostatitis-chronic pelvic pain syndrome.** N Engl J Med. 2008 Dec 8;359(25):2663-73).

cp01_long.sas7bdat – SAS dataset used in primary analysis
primary manuscript.sas – SAS program file to reproduce tables published in primary manuscript.
format.sas - SAS program file providing variable format library for categorical variables in primary analysis file.
cpsiresp_metan.dta- STATA calculation (using the *metan* procedure) of 95% CI for CPSI primary endpoint.
anal.sas – SAS program file for calculation of exact conditional test adjusted for clinical center, CPSI primary endpoint
cpsimetan.log – Output from STATA *metan* procedure for CPSI primary endpoint analysis
cpsimetan.txt – STATA code for calculation of center-adjusted 95% CI, CPSI primary endpoint.
anal.log – Output from procedure to calculate CI rate difference adjusting for center-to-center variability using cpsiresp_metan.sas7bdat
graresp_metan.dta–STATA calculation (using the *metan* procedure) of 95% CI for GRA response measure
grametan.log – Output from STATA *metan* procedure for GRA response outcome measure
grametan.txt – STATA code for calculation of center-adjusted 95% CI, GRA response outcome measure

The remaining files were used for tracking specific activities for study subjects:
elig.sas7bdat – tabulation of checklist used to determine eligibility
exam.sas7bdat – tabulation of number of subjects with a completed physical exam form
prescr.sas7bdat – tabulation of persons screened prior to consent
urine.sas7bdat – tabulation of number of subjects who had a laboratory urine screening test

4. Overview and Publications

This directory contains 3 files: 1) a listing of published articles for the CPCRN2 Network; 2) a published article on the Alfuzosin Study; and 3) a summary overview of the study prepared by the DCC and a listing of wider publications conducted by the CPRCRN network under whose auspices the Alfuzosin Study was conducted.

5. Data Set Integrity Check (DSIC)

As a partial check of the integrity of the CPCRN2-Alfuzosin dataset archived in the NIDDK data repository, a set of tabulations was performed to verify that published results can be reproduced using the archived dataset. Analyses were performed to duplicate selected results for the data published by Nickel et al [1] in the *New England Journal of Medicine* in December 2008. Complete results are presented in the DSIC folder of the Official Archive.