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AWARD NUMBER: W81XWH-08-2-0069

TITLE: A Placebo-Controlled Augmentation Trial of Prazosin for Combat Trauma
PTSD

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REPORT DATE: June 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 1 June 2009		2. REPORT TYPE Annual		3. DATES COVERED 1 June 2008 – 31 May 2009	
4. TITLE AND SUBTITLE A Placebo-Controlled Augmentation Trial of Prazosin for Combat Trauma PTSD				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-08-2-0069	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Murray Raskind, M.D., Elaine Peskind, M.D., Kris Peterson, M.D., Charles Engel, M.D. E-Mail: murray.raskind@va.gov				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Seattle Institute for Biomedical and Clinical Research Seattle, WA 98108				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This study consists of a 14-week, two parallel group, randomized placebo controlled trial to evaluate the efficacy and tolerability of the alpha-1 adrenergic antagonist, prazosin, for reducing trauma nightmares and sleep disturbance and improving global function and sense of well-being, in 210 OIF and OEF combat-exposed returnees with PTSD and persistent traumarelated nightmares and disrupted sleep. A secondary aim is to assess efficacy of prazosin for reducing total PTSD symptoms, reducing symptoms of depression, improving quality of life, and reducing alcohol craving.					
15. SUBJECT TERMS PTSD, prazosin, trauma nightmares, sleep					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	5	19b. TELEPHONE NUMBER (include area code)

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Introduction

The primary objective of this randomized, double-blind, placebo-controlled trial is to evaluate the efficacy and tolerability of the alpha-1 adrenergic antagonist prazosin compared to placebo for combat stress-related nightmares, sleep disturbance, and overall function in trauma-exposed service members. The secondary objective of this trial is to assess the efficacy of prazosin for reducing total PTSD symptoms, reducing symptoms of depression, improving quality of life, and reducing alcohol use.

210 male and female returning troops from Operation Iraqi or Enduring Freedom (OIF/OEF), who manifest persistent combat stress-related nightmares and sleep disturbance, will be enrolled in the study. Participants will undergo a flexible dose titration period followed by optimal dose treatment for a total of 15 weeks including the titration period. Primary and secondary outcome measures will assess nightmares, sleep disturbance, other stress-related symptoms, depression, global function, and quality of life and will be administered every four weeks. Data will be analyzed for significant differences among treatment groups using generalized estimating equations.

Body

We are happy to report that all regulatory approvals have been received at VA Puget Sound and Walter Reed AMC, including HRPO approval and conditional approval (as of 6/23/09) has been received from the Madigan AMC IRB (estimated complete approval by 7/15/09). Given that our recruitment mechanisms and contacts are in place at all sites, we anticipate entering two subjects per week into the trial beginning 7/6/09 at Walter Reed AMC and VA Puget Sound and 8/1/09 at Madigan AMC.

Beginning July 2009 at Walter Reed AMC and VA Puget Sound, and August 2009 at Madigan AMC, we will screen at least 5 potential eligible OIF/OEF returnees weekly at each site to enable us to enter at least 2 appropriate and consented subjects at each site per month (total 6 per month across all sites). With final approval at VA Puget Sound received, ten potential subjects have been scheduled for screening the first week after the July 4th weekend.

Key Research Accomplishments

- Protocol, consent form, and study materials approved by regulatory bodies.
- CRADA between CIRO, DCI, and HJF prepared and ratified (Walter Reed AMC).
- Study materials, including eligibility, baseline, and follow-up assessments developed, approved, and ready for assembly.
- Study ready to begin recruitment and enrollment of participants.

Reportable Outcomes

Pending

Conclusions

Pending

References

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Appendices

N/A

Supporting Data

Pending