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Award Number: W81XWH-08-2-0075

TITLE: Prazosin for Treatment of Patients With PTSD and Comorbid Alcohol Dependence

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REPORT DATE: July 2010

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT:

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-07-2010	Annual	1 JUL 2009-30 JUN 2010

4. TITLE AND SUBTITLE
Prazosin for Treatment of Patients With PTSD and Comorbid Alcohol Dependence

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-08-2-0075

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
DR. Ismene Petrakis

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Yale University New Haven, CT 06520

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

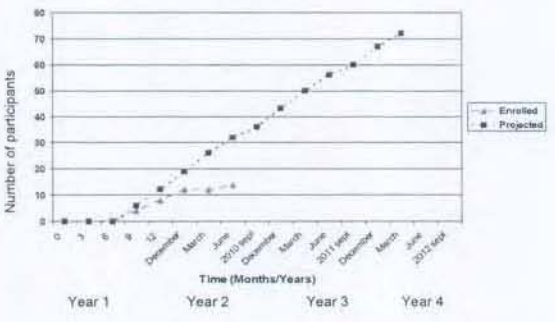
Background: There is a high rate of comorbidity with alcohol dependence (AD) and post traumatic stress disorder (PTSD). The rates of PTSD among individuals with AD are at least twice as high as those in the general population. In addition, alcohol dependence is the most common comorbid condition in men with PTSD. Despite this, little is known about how to best treat individuals with comorbid AD and PTSD. The use of an alpha-1 adrenergic receptor antagonist represents a novel approach to treatment that may target symptoms of both AD and PTSD. There is evidence of common neurobiological mechanisms that underlie both AD and PTSD. Prazosin is an alpha-1 adrenergic receptor antagonist that has been used successfully in the treatment of trauma nightmares and sleep disturbance in combat veterans with PTSD, and alcohol dependence. Objective: The objective of this study is to evaluate the efficacy of prazosis (16mg) versus placebo in reducing alcohol consumption and decreasing symptoms of PTSD in patents with comorbid AD and PTSD. Methods: One hundred and twenty participants with the current diagnosis of AD and PTSD will be enrolled in a 13-week trial. They will be assigned, in a double-blind fashion, to either prazosin or placebo as effective treatments for reducing alcohol consumption and PTSD symptoms in patients with both AD and PTSD.

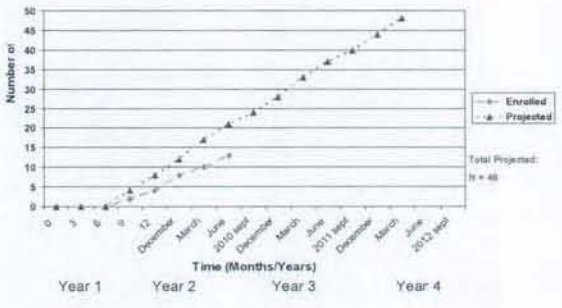
15. SUBJECT TERMS
PTSD, alcohol dependence, treatment, Prazosin

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	4	**19b. TELEPHONE NUMBER** *(include area code)*

INTRODUCTION: The objective of this research is to evaluate the efficacy of Prazosin 16mg versus placebo in reducing alcohol consumption and decreasing symptoms of PTSD in patients with comorbid AD and PTSD. We hypothesize that Prazosin will significantly reduce the number of drinking days and reduce the symptoms of PTSD compared to placebo in patients with AD and PTSD. This is a double-blind, multi-site, randomized, 13-week, treatment trial. The recruitment for this study is planned for 4 years.

BODY: This report covers the period of the second year of funding. Our goals for the second year were to: continue subject recruitment (in the first phase), develop and implement new avenue for recruitment, create new liaisons for recruitment, and follow patients already recruited in the study. The goals for this year have been accomplished regarding continuous recruitment as well as initiation and implementation of new recruitment strategies. However, our goal to recruit a total of 53 subjects has not been reached. Below we provide graphical representation of our recruitment to date in relationship to the goals we outlined in our statement of work. Our recruitment is progressing, and we have developed and implemented a number of strategies to increase recruitment in the second year. At the West Haven site, we have allocated resources for newspaper advertisement, and we created new liaisons in the community. Our recruitment has improved but in order to reach our recruitment goal we need to recruit more subjects into the study. We believe that one strategy that will significantly increase recruitment will be to expand the inclusion criteria in this study and include non-veterans with AD and PTSD (while aggressively continuing to recruiter veterans). This change in the inclusion criteria has been submitted to the DOD for review and we are awaiting decision.





Included in this report is a table that outlines our recruitment success – at both sites - to date.

Site	# Ss that have signed consent	# Ss enrolled	Ratio of Ss to target
West Haven	46	14 please note that 2 subjects are presently awaiting randomization	14/72
Bedford	23	13	13/48

KEY RESEARCH ACCOMPLISHMENTS: This study is in its early stages.

REPORTABLE OUTCOMES: The PI gave a presentation at the American Psychiatric Association Annual meeting on the comorbidity of PTSD and alcohol dependence. An abstract was also submitted for the upcoming Military Health Research Forum.

CONCLUSION: To date, our sample size does not permit statistical analysis of the data. We can only report that to date, medication has been well tolerated. For this reporting period there was one report of a serious adverse event at Bedford. Participant was hospitalized for an allergic reaction (rush). The blind was broken at the request of the Bedford HIC and the event was deemed unrelated to study participation. Also, there were no reports of any adverse events that were related to study participation.

REFERENCES: None, to date.

APPENDICES: None, to date.