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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 prazosin (16mg) versus placebo in reducing alcohol consumption and decreasing symptoms of PTSD in patients with comorbid AD and PTSD. **Methods:** One hundred and twenty participants with a 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.

Findings: No findings are yet available for this study. **Significance:** This project will be the first to compare prazosin to placebo as effective treatments for reducing alcohol consumption and PTSD symptoms in patients with both AD and PTSD.

15. SUBJECT TERMS

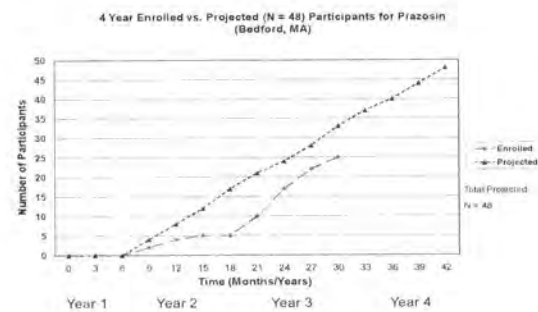
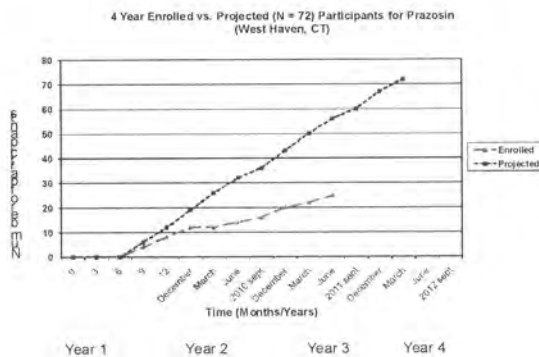
PTSD, alcohol dependence, treatment, Prazosin

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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 third year of funding. Our goals for the third year were to: continue subject recruitment, 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 83 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.



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	69	25	25/72
Bedford	44	26	26/48

KEY RESEARCH ACCOMPLISHMENTS: This study is ongoing and the sample size is not large enough for statistical analysis of the data at this time.

REPORTABLE OUTCOMES: The PI gave a presentation at the American Psychiatric Association Annual meeting on the comorbidity of PTSD and alcohol dependence in 2009. An abstract was also submitted for the Military Health Research Forum. A poster was presented at the Research Society of Alcoholism meeting in Atlanta, GA (June, 2011) comparing demographic characteristics of patients with dual diagnosis of AD and PTSD and patients with only AD diagnosis.

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 – death of a participant. AE reports were submitted to VA and Yale IRBs and a report was also sent to the DOD. At this time the autopsy report is pending and the event has been deemed unrelated to study participation.

REFERENCES: None, to date.

APPENDICES: None, to date.