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TITLE:
Hyperbaric Oxygen therapy in the Treatment of Chronic Mild-Moderate Blast-Induced Traumatic Brain Injury PCS and PTSD

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The purpose of the study is to see if a four-week course of forty low-pressure HBOT's can significantly improve symptoms and cognitive function in military veterans with mild-moderate blast-induced TBI/PCS with PTSD. The scope of the project is to recruit, enroll, treat, and test 50 subjects in a randomized controlled double-blind study within 18 months. There are no results to report at this time since the study has not begun. The study is still in the pre-enrollment regulatory process. An FDA IND was granted on 10/24/2013. A decision on a Special Protocol Assessment (SPA) application attached to this IND is due by November 10, 2013. The SPA decision will determine the final protocol that will be allowed for this study. The study will commence shortly thereafter.

15. SUBJECT TERMS
HBOT: hyperbaric oxygen therapy; TBI: traumatic brain injury; PCS: post-concussion syndrome; PTSD: post-traumatic stress disorder

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I. INTRODUCTION

Mild-moderate blast-induced traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) affect 11-28% and 13-17%, respectively, of U.S. combat troops returning from Iraq and Afghanistan. Evidence-based medicine exists for PTSD, but there is no effective treatment for the post-concussion syndrome (PCS) of mild-moderate TBI nor the combined diagnoses of PCS and PTSD. Between the Fall of 2008 and end of 2010, the P.I. conducted a pilot trial of hyperbaric oxygen therapy (HBOT 1.5 atmospheres absolute) in military veterans with both TBI/PCS and PTSD that achieved substantial symptomatic and cognitive improvements in the subjects. Preliminary results were published 11/2011 in the Journal of Neurotrauma (http://www.liebertonline.com/doi/abs/10.1089/neu.2011 .1895). The purpose of the proposed study is to see if a four-week course of forty low-pressure HBOT's can significantly improve symptoms and cognitive function in military veterans with mild-moderate blast-induced TBI/PCS with PTSD using a randomized controlled design. The scope of the project is to recruit, enroll, treat, and test 50 subjects within 18 months. Due to delays in obtaining regulatory approval the study will be 15 months in duration and will be augmented by participation of Oklahoma State University School of Medicine Department of Hyperbaric Medicine.

II. BODY

The research accomplishments associated with the tasks in the Statement of Work are as follows:

A. Obtain IRB approval prior to award date: IRB approval was obtained from LSU School of Medicine 12/10/2010. VA IRB approval was not obtained until ORP approval could be secured. Second level ORP approval was held pending FDA IDE procurement. FDA Pre-IDE Request from the fall of 2009 was lost at the FDA. The FDA re-instituted the pre-IDE application in the summer of 2010 and a decision was issued in 5/2011 diverting the P.I. to the FDA Center for Drug Evaluation and Research. The P.I. requested a face-to-face Pre-IND meeting with the FDA that was granted 11/2011. The meeting was held on 3/12/2012. Due to the physical impossibility of performing the pressure control group recommended by the FDA in the PIND meeting, the necessity of having the data from the Department of Defense multi-dosing HBOT/TBI trials for a pre-market HBOT IND application, and the desire to have peer-reviewed literature published on the outcomes in the DoD HBOT/TBI studies the IND was not submitted until 9/26/2013. The IND was granted on 10/24/2013, but a Special Protocol Assessment (SPA) ruling is pending and due by 11/10/2013. The SPA

will determine the final protocol for the study. That final protocol will be submitted to TATRC and ORP.

B. Recruit sufficient numbers of appropriate subjects to complete the study within project period: The study is still in the pre-study regulatory approval process. No recruitment has occurred.

C. Enroll, test, and treat 50 subjects within 17 months from award date: The study is still in the pre-study regulatory approval process. No enrollment has occurred. Due to the above delays the 50 subjects will need to be recruited, enrolled, tested, and treated within 15 months. Although the timeline is shortened the participation of Oklahoma State University should make recruitment goals achievable.

D. Analyze data and submit a manuscript for peer-reviewed publication within 24 months of funding: A more accurate statement of this goal would be a publication within 24 months of first enrollment. At this point the study is still in the pre-study regulatory approval process and no data has been generated.

III. KEY RESEARCH ACCOMPLISHMENTS

There are no key research accomplishments since the study has not begun.

IV. REPORTABLE OUTCOMES

There are no reportable outcomes since the study has not begun.

V. CONCLUSION

The study is still in the pre-approval regulatory stage. IND was obtained on 10/24/2013, but final protocol confirmation by the FDA is awaiting the Special Protocol Assessment ruling which is due by 11/10/2013. As soon as the SPA is obtained a final protocol will be submitted to TATRC and ORP. The study should begin shortly thereafter.

VI. REFERENCES

There are no references.

VII. APPENDICES

There are no appendices.

VIII. SUPPORTING DATA

There is no supporting data.