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Table of Contents

Introduction…….……..…..... 1

Body……. 1

Key Research Accomplishments…….…… 1

Reportable Outcomes…….. 2

Conclusions……... 2

References…….. None

Appendices..... None

ABSTRACT

The main objective of this application is to determine whether D-cycloserine (DCS) can enhance the efficacy of social skills training (SST) in the treatment of children and young adolescents with autism spectrum disorders (ASDs). We will evaluate the efficacy, tolerability, and last effects of DCS given one hour prior to each of 10 weekly SST sessions for the treatment of social impairment in 52 children and young adolescents (ages 5-11 years) with ASDs during a randomized placebo-controlled trial. The safety and tolerability of DCS and dirability of treatment response will also be examined. Institutional IRB and Department of Defense Human Research protections Office approvals have been obtained. Staff have been hired and trained on study procedures. The first group of 6 youth (4 with ASD and 2 normally developing children) have completed the first SST group and the second group is active in the trial due to complete 10 weeks of treatment in November. We have a set schedule for 4 groups per year. We recently received IRB approval of an amendment to allow for enrollment of youth with stable seizure disorders and youth who take up to two concomitant psychotropic non-glutamatergic drugs. In addition we have received IRB approval to add use of the Autism Diagnostic Observation Schedule to better characterize ASD pathology.

INTRODUCTION

The long-range goal of this research is to identify better treatments for the core social and communication impairment of autism spectrum disorders (ASDs). The main objective of this application is to determine whether D-cycloserine (DCS) can enhance the efficacy of social skills training (SST) in the treatment of children and young adolescents with ASDs. The central hypothesis is that DCS will enhance the learning of social skills over the course of 10 weeks of SST. To test this hypothesis, we will evaluate the efficacy of DCS given one hour prior to each of 10 weekly SST sessions for the treatment of social impairment in 52 children and young adolescents (ages 5-11 years) with ASDs during a randomized placebo-controlled trial. The safety and tolerability of DCS and durability of treatment response will also be examined.

BODY

Final IRB approval was obtained August 5, 2009. Initial revisions requested by the Department of Defense Human Research Protections Office (HRPO) were received and processed in an IRB amendment approved on December 25, 2009. Final revisions then requested by the HRPO were submitted to our IRB and final approval was received February 4, 2010.

During this funding, year staff have been hired and trained to conduct this study. Source documents were created. Staff were trained on the execution of the protocol and on the outcome measures employed in the protocol. Procedures for dispensing and tracking drug were established with Investigational Drug Services. Arrangements for obtaining drug and matching placebo were made.

The SST curriculum including lesson plans, homework assignments, and parent notes was finalized. Supplies for the SST were purchased. Visual supports for the curriculum were created. A procedure for coding and ensuring treatment and rating fidelity was established.

The first three SST groups have been completed and the fourth group is ongoing. Additionally two typically developing children were enrolled in each group.

The fourth group started in March 2011 and will be completed in May. The fifth group is scheduled to begin in late May 2011.

We have set a schedule to conduct four subject groups per 12 months until enrollment is completed.

KEY RESEARCH ACCOMPLISHMENTS (since last report)

- Began the fourth SST group enrolling 6 youth (4 with ASDs, 2 with normal development/peer trainers) with the group set to finish 10 weeks of intervention by the end of May 2011.

- Have recruited and screened ASD and normal development peer trainers for the next group set to begin at the end of May 2011.
- Received approval with the IRB to add a parent/family satisfaction measure to better assess the ‘real world” potential study benefits from the perspective of a caregiver.

REPORTABLE OUTCOMES

We expect most of the reportable outcomes of this award will be realized in the later years of the project.

CONCLUSION

Since this is a clinical trial, the results will be analyzed after all subject data collection has been completed (Year 5).