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TITLE: A Randomized Placebo-Controlled Trial of D-Cycloserine for the Enhancement of Social Skills Training in Pervasive Development Disorders

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14. 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. We will evaluate the efficacy, tolerability, and lasting 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 7-14 years) with PDDs during a randomized placebo-controlled trial. The safety and tolerability of DCS and durability of treatment response will also be examined. Institutional IRB and Department of Defense Human Research Protections Office approval have been obtained. Staff have been hired and trained on study procedures. Supplies have been purchased. Children participating in the first group have been screened and will begin on March 30, 2010.					
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Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	4
Reportable Outcomes.....	4
Conclusion.....	4
References.....	5
Appendices.....	5

INTRODUCTION:

The long-range goal of this research is to identify better treatments for the core social and communication impairment of autistic disorder (autism) and other pervasive developmental disorders (PDDs). 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. The central hypothesis of this project is that DCS will enhance 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 7-14 years) with PDDs during a randomized placebo-controlled trial. The safety and tolerability of DCS and durability of treatment response will also be examined.

BODY:

The study was initially submitted to our institutional IRB on May 26, 2009. It was provisionally approved on June 16, 2009. Final IRB approval was obtained August 5, 2009. Initial revisions requested by the Department of Defense Human Research Protections Office (HRPO) were received by November 13, 2009. These were submitted to the IRB on November 25, 2009, and approved on December 25, 2009. Final revisions requested by HRPO were submitted to our IRB on January 7, 2010 and were approved on February 4, 2010.

During this first year of funding, additional staff were hired and trained on the protocol and clinical outcome measures. Source documents were created. A randomization list was established. Procedures for dispensing drug in conjunction with the Investigational Drug Services were established. Arrangements for obtaining compounded 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 ensuring treatment fidelity and inter-rater reliability has been established.

Institutional IRB approval was received on August 5, 2009. We have screened 6 children with PDD for the first group, of which 4 children met eligibility criteria. Two additional typically developing children have been consented and trained to act as peers in the SST group. The first group is scheduled to begin on March 30, 2010.

KEY RESEARCH ACCOMPLISHMENTS:

- Institutional IRB and Department of Defense HRPO Approval
- Research Team trained and ready to conduct protocol
- Initial group of patients screened and ready to begin treatment protocol

REPORTABLE OUTCOMES:

We expect that 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).

REFERENCES:

None.

APPENDICES:

None.

SUPPORTING DATA:

None.