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PROTOCOL APPLICATION FORM Human Subjects Research Stanford University

Title: Nitrous Oxide for Posttraumatic Stress Disorder (PTSD): A Phase IIa Trial

Clinical Study

Purpose:

PTSD seriously disrupts the lives of many Veterans. Current first-line pharmacological treatments often fail to bring meaningful improvement, leaving these Veterans with distressing and impairing symptoms. Developing more effective and more rapidly effective therapeutic options is critical. The purpose of the study is to assess efficacy of nitrous oxide in PTSD and the duration of its short-term therapeutic effects.

Objectives:

1. To determine the efficacy of nitrous oxide in PTSD
2. To examine the safety of nitrous oxide administration in PTSD

Design:

The clinical study design is a randomized placebo-controlled clinical trial including two groups: Group 1) “Active Treatment” Nitrous oxide group, and, Group 2) “Active Comparator/Placebo group.”

Methods:

The study’s first phase is the Screening phase, to assess eligibility via inclusion and exclusion criteria. During the Baseline phase, participants will be rated for PTSD. Participants will then enter the Randomization phase and be randomized (1:1) to receive either an admixture of up to 50% nitrous oxide and 50% oxygen plus IV saline ("active treatment") plus IV saline or 50% nitrogen and 50% oxygen plus 0.045mg/kg midazolam ("active comparator") for 1 hour. During the Treatment phase, the gas mixture will be administered via facemask connected to a standard anesthesia machine at 4-8 L/min. Participants will be continuously monitored (EKG, BP, O2) during treatment per the American Society of Anesthesiologists standard and observed for an additional four hours of recovery supervised by an attending-level anesthesiologist. To examine changes in PTSD, symptoms will be reassessed 7 days (1 week) post-administration. Unexpected adverse effects of nitrous oxide will be recorded at each time point.