

WESTERN IRB PROTOCOL

National Brain Injury Rescue and Rehabilitation Study (NBIRR-01)

Inclusion - Exclusion Criteria [as published at www.clinicaltrials.gov]

Inclusion Criteria:

1. Any 18-65 year-old patient with mild-moderate TBI or PTSD. (If a military injury, subject may be active duty or a veteran. If active duty, participants will have to voluntarily contact NBIRR.)
2. Have demonstrated a >20% decrement (compared to pre-deployment baseline) in ANAM composite score or specific sub-score with regard to "simple reaction time" and/or "procedural reaction time".
3. Have a diagnosis of TBI, chronic TBI/PCS or TBI/PCS/PTSD or PTSD made by a military (military etiology of blast injury) or civilian specialist.
4. Negative pregnancy test in females.
5. Less than 90% on the Percent Back to Normal Rating Scale. (If patient is considered 100% normal before TBI, patient should be less than 90% normal for entry into the study).

Exclusion Criteria:

1. Pulmonary disease that precludes HBOT (e.g., asthma unresponsive to medication, bullous emphysema).
2. Unstable medical conditions that are contraindicated in HBOT (e.g. severe congestive heart failure or heart failure requiring hospital emergency evaluation or admission in the previous year).
3. Severe confinement anxiety (claustrophobia; e.g., patients who require anesthesia conscious sedation for MRI or who cannot go in elevators).
4. Pregnancy.
5. Other pre-TBI neurological diagnoses.(seizure disorders, multiple sclerosis, Parkinson's, Lyme, etc.)
6. Participation in another experimental trial with active intervention.
7. High probability of inability to complete the experimental protocol (e.g. terminal condition).
8. Past or current history of mental retardation unless diagnosed post TBI (baseline IQ \leq 70).
9. Pre- or post-TBI history of systemic illness with impact on central nervous system. (Principal Investigator in consultation with study sponsor Medical Officer will make the ultimate decision).
10. Any pre-existing chronic infection not related to battlefield injuries or government service.