Theta Burst Stimulation for Headaches after Traumatic Brain Injury

Status: Recruiting

Eligibility Criteria

Age: 18 Years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

? Veterans receiving services through the MVAHCS; ? History of mild to moderate TBI according to VA/DoD Clinical Practice Guidelines (2009); ? Post-traumatic headaches defined by International Classification for Headache Diagnosis 3rd Edition (ICHD-3) guidelines with the following criteria present: o Headaches developing within seven days following trauma or injury to the head and/or neck o Headaches persisting beyond three months; ? Chronic daily headaches defined by clinical standards with the following criterion present: o 15 or more headache days per month; ? Men and women 18-75 years of age; ? Possess a smartphone and agree to use the EMA application on their personal device; ? Capable and willing to provide voluntary informed consent

Exclusion Criteria:

? History of severe TBI according to VA/DoD Clinical Practice Guidelines (2009); ? Current (within six months of enrollment) psychosis and mania; ? Current (within one month of enrollment) substance dependence: o Does not include dependence on opioids for chronic pain when the medication is taken as prescribed; ? Personal history of epilepsy or seizure disorder: o Does not include seizures therapeutically-induced by electroconvulsive therapy (ECT) or identified as a single seizure event (based on the principal investigator?s judgement); ? Metal particles in the eye or head (exclusive of the mouth) (e.g., shrapnel, fragments from welding or metalwork, etc.); ? Implanted medical device controlled by physiologic signals (e.g., pacemakers, defibrillators, etc.) or implanted medical device above the clavicle (e.g., aneurysm clips, shunts, stimulators, cochlear implants, electrodes, etc.); ? Significant neurological disorder/injury or abnormal structural brain imaging that would impact risk (based on the principal investigator?s judgement and research literature); ? Unstable physical disease (e.g., severe heart disease); ? Current use of medications with significant potential for lowering seizure threshold; ? Current benzodiazepine usage at a dose higher than 3mg of lorazepam or equivalent; ? ECT or cortical energy exposure within one month of enrollment (including participation in any other neuromodulation treatments or studies); ? Current (within one month of enrollment) participation in another interventional study that would impact the results of this research; ? Inadequate communication (e.g., language barrier); ? Women who are pregnant, trying to become pregnant, or breastfeeding; ? Women of childbearing age/potential who are not using a medically-accepted form of contraception when sexually active

Conditions & Interventions

Conditions:
Brain & Nervous System, Brain Injuries, Traumatic, Post-Traumatic Headache, Quality of Life, Transcranial Magnetic Stimulation
Keywords:
TBI, TMS, headache

More Information

Description: The primary objective of this study is to investigate the safety and efficacy of theta burst stimulation (TBS) for the management of post-traumatic headaches to improve outcomes and quality of life for individuals who have suffered a traumatic brain injury (TBI). To improve tolerability and logistical burden, we have developed a novel design whereby participants will receive three doses of TBS on alternate days of the week. This design will allow us to assess efficacy while leveraging an accelerated treatment course (nine stimulation sessions per week). We have three specific aims: Specific Aim 1. To determine the efficacy and safety of TBS for the treatment of post-traumatic headache among individuals who have sustained a mild TBI. Hypothesis 1a: TBS will be safe, well-tolerated, and reduce the number of headache days. Hypothesis 1b: TBS will improve function and quality of life outcomes. Specific Aim 2: To determine the efficacy and safety of an accelerated time-course of TBS for the management of post-traumatic headache. Hypothesis 2a: The accelerated-time course will be safe, welltolerated, and improve quality of life outcomes. Hypothesis 2b: The accelerated time-course will produce greater and faster improvement in headache symptoms than that reported in the literature for standard repetitive transcranial magnetic stimulation (rTMS) protocols. Specific Aim 3: To examine the durability of treatment response to accelerated TBS during a one-month observational period. Hypothesis 3: Accelerated TBS will result in enduring treatment response of posttraumatic headache symptoms over the follow-up period.
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