

Study of Bacopa in Gulf War Illness Patients

NCT04927338

Status	RECRUITING
Phase	Phase 2
Sponsor	Nova Southeastern University
Enrollment	170 participants

Key Eligibility Criteria

Inclusion (8)

- Born in years 1942 to 1978
 - Served in the Gulf War theater for any period between August 1990 and July 1991
 - Meets modified Kansas case definition criteria and CDC case definition for Gulf War Illness (GWI). The modified Kansas definition, which includes the CDC criteria includes:
 - Allowance for normal illnesses of aging, such as hypertension and diabetes if the conditions are treated and are in demonstrable stable and normal ranges at the time of screening and assessment.
 - Allowance of stable comorbid conditions such as post-traumatic stress disorder (PTSD), major depressive disorder (MDD), and traumatic brain injury (TBI) that have not required hospitalization in the 5 years prior to recruitment. Severe TBI is excluded.
- ... and 3 more (see full listing online)

Exclusion (21)

- They are scheduled for a surgery during the period of study participation, had minor surgery within 3 months prior to screening, or had major surgery within 6 months prior to screening,
 - Self-report of current untreated major depression with psychotic or melancholic features (as determined by self-report), schizophrenia, bipolar disorder, delusional disorders, dementias of any type, or substance abuse during the last two years (excluding cannabis products),
 - Any serious allergic disease (self-report), possibly resulting in anaphylaxis, such as food/drug allergies, including allergic asthma, or allergy to any ingredient of the active product or placebo, including allergies to FD&C Yellow No. 5 (tartrazine),
 - Renal disease (self-report; laboratory results: renal insufficiency with serum creatinine > 2.0 mg/dL or eGFR < 44 ; or currently on renal dialysis),
 - Hepatic insufficiency (bilirubin > 2.5 mg/dL or transaminases > 3 x the upper limit of normal (ULN)). Participants with Gilberts syndrome are eligible for the study if other liver function tests are normal, regardless of bilirubin level,
- ... and 16 more (see full listing online)

Locations (1 total)

Nova Southeastern University, Davie, Florida, United States