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TITLE: Confirmation of the Low-Glutamate Diet as a Treatment for Gulf War Illness

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CONTRACTING ORGANIZATION: American University

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14. ABSTRACT: The proposed research titled "Confirmation of the Low Glutamate Diet as a Treatment for GWI" aims to address the overarching challenge of eliminating the health consequences associated with GWI and revolutionizing treatment. Background: Multiple of the exposures from the Gulf War are known to cause downstream release of glutamate and excitotoxicity, and prior GWI research has also reported evidence of neuroinflammation and oxidative stress as key components of the illness. Excitotoxicity, inflammation, and oxidative stress have the unique ability to influence one another in a self-sustaining manner, forming a neurotoxic triad. Thus, neurological disorders like GWI may require treatments which address all three of these components to result in optimal improvements. The rationale for the proposed clinical trial comes from the very exciting data from our recently completed GWI trial testing the effects of the low glutamate diet on the symptoms of GWI in 40 veterans. We observed dramatic improvements in overall symptom number (with an average of 9 symptoms remitting), significant reductions in pain, fatigue, depression, anxiety, and PTSD; with concurrent significant

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NONE LISTED

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Introduction

This is a confirmatory clinical trial testing the low glutamate diet as a treatment for Gulf War Illness. We aim to recruit a total of 160 veterans to three study sites. Forty subjects each will be locally recruited to Boston University and Nova Southeastern University in Florida, and 80 subjects will be recruited from a national sample to American University in Washington DC. The goal of this study is to confirm the earlier improvements noted in the last study testing the low glutamate diet as a treatment for Gulf War Illness, and to expand on that previous work, by investigating the mechanisms behind how the diet works, including effects on neurotransmission, excitotoxicity, inflammation (both peripheral and central), and oxidative stress.

We have now completed the first year of the grant cycle, and are currently behind schedule at two of the three sites, due to delays in getting approvals. The DC site is currently close to being on track, with 18 subjects having been recruited by the end of year 1, as opposed to 22 as the estimated recruitment in the SOW. Boston University has finally received approval from their IRB to defer to AU, so they now can begin enrolling subjects. Similarly, the Florida site has just completed their mock run through and are now ready to receive subjects. NSU has two people consented to date, but the subjects have not yet been seen. In our SOW, we had estimated that Boston and Florida would have each recruited 11 subjects in the first year, so both sites are behind schedule.

Our goal for the upcoming year is to make-up lost time and to catch up on recruitment. In DC, we hope to recruit 40 subjects over the next fiscal year, and to have at least 20 subjects recruited at each of the other sites.

Keywords

Gulf War Illness, GWI, multi-symptom illness, neurological symptoms, dietary treatment, glutamate, excitotoxicity, oxidative stress, neuroinflammation, micronutrients, nutrition

Accomplishments

Thus far, we have successfully gotten approvals (including continuing review approval) for all 5 study sites (including the three recruitment sites above as well as Mass General Hospital and Georgetown University, which are our two imaging sites), as well as approvals from OHRO. The study is registered at ClinicalTrials.gov and we have recruited 18 of 160 subjects by the end of year one.

Impact

The only impact we have had to date is on the individual veterans who have participated in the study; however, these have been exciting, with subjects reporting improvements in pain, fatigue, sleep, mood, cognitive function, and gastrointestinal symptoms after one month on the diet.

Changes/Problems

None to report.

Products

None to report.

Participants & Other Collaborating Organizations

The participants are veterans of the Gulf War who fulfill the CDC and Kansas City criteria for Gulf War Illness. Our subjects have been recruited through Facebook and have come to DC from across the country. We have been especially successful at recruiting women so far, with 15/18 or 83% being female veterans. We have also successfully recruited some diverse veterans with two people identifying as African American, two people identifying as Hispanic, and one Asian American.

Our collaborating institutions include Boston University and Mass General Hospital (as an imaging site) in Boston, MA; Georgetown University in Washington DC (also an imaging site); and Nova Southeastern University in Ft. Lauderdale, FL.

Special Reporting Requirements

None.

Appendices None.