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TITLE: Identifying Immune Drivers of Gulf War Illness Using Novel Daily Sampling Approach

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14. ABSTRACT The major aim of this research project is to identify chemicals in the blood that are associated with the symptoms of Gulf War Illness (GWI). We are targeting an enrollment of 60 men (40 veterans with GWI, 10 veterans with no GWI, and 10 with fibromyalgia) over this 3-year project. This report represents our first annual update since starting the project. During our first year, we have screened 103 participants, enrolled 14, and have 2 currently completing the protocol. We have had no attrition of individuals who have consented to the study. In Year 2, our major goal is to increase our recruitment efforts, including using the Persian Gulf War Registry database and the Defense Manpower Data Center database. We have not yet conducted assays on any blood samples, and do not have preliminary results to present at this time.					
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Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	5
Key Research Accomplishments.....	6
Reportable Outcomes.....	7
Conclusion.....	8
References.....	9
Appendices.....	10

Introduction

Gulf War Illness (GWI) is a debilitating disease that is estimated to affect at least 175,000 veterans in the United States, causing pain sensitivity, profound fatigue, cognitive dysfunction, chronic headaches, gastrointestinal problems, and other symptoms. The underlying pathology of GWI is still unclear, posing a severe obstacle to both the diagnosis and treatment of the disorder. In order to make gains in curing GWI, it is essential that we develop objective, physiologic-based tests for the disorder, and identify physiological targets for treatments. The major aim of this research project is to identify aspects of the immune system that are dysregulated in veterans with Gulf War Illness. A second aim is to determine whether identified immune system dysregulations are similar to those found in men with fibromyalgia. To accomplish those aims, we are recruiting 40 male veterans diagnosed with Gulf War Illness, as well as 10 healthy veteran controls, and 10 males with fibromyalgia. Participants complete 25 consecutive days of blood draws and provide daily reports of symptom severity. Analyses will then be conducted to identify immune system factors that correlate with day-to-day symptom fluctuations. Ultimately, this information may be used to develop new treatments that specifically target the pathophysiological mechanisms of Gulf War Illness.

Body

Below, we highlight the ten tasks identified in our statement of work, and report our progress.

Task 1: Team review and progress meetings (ONGOING)

We are on track with this task. We are continuing to have meetings throughout the study protocol to discuss any medical issues that may arise associated with the protocol, and to re-assess recruitment strategies.

Task 2: Submission of documents for regulatory approvals (COMPLETED)

We have submitted all regulatory documents and have received all necessary approvals to initiate the study.

Task 3: Start up (COMPLETED)

We have fully trained all personnel and have begun the study protocol.

Task 4: Advertisement (ONGOING)

We are on track with this task. We will continue to advertise through a variety of venues to recruit participants.

Task 5: Screen GWI participants for study (ONGOING)

We projected being 25% complete with enrollment by the end of Year 1. We are currently at 23%. We are slightly below our target because we were not able to start the study protocol until May of 2013, so we have not had a full year to recruit participants. We do not anticipate any problems with recruitment going forward.

Task 6: Recruit control groups (ONGOING)

We are on target to complete our control group enrollment by mid-Year 2.

Task 7: Collection of blood samples and self-reported symptom data (ONGOING)

We are on track with this task and will continue to collect samples and data throughout Years 2 and 3.

Task 8: Quantification of biochemicals in blood samples (NOT YET STARTED)

This task is planned to begin in Year 3.

Task 9: Analyses (NOT YET STARTED)

This task is planned to begin in Year 3.

Task 10: Preparation of final report and publications (NOT YET STARTED)

This task is planned to begin in Year 3.

Key Research Accomplishments

The project is going as planned and we have not encountered significant obstacles to running the study. Analyses are planned to be carried out in Year 3, and we anticipate having research accomplishments to report at that time.

Reportable Outcomes

We are still collecting data for this project. We do not anticipate having reportable outcomes until the end of Year 3, once analyses have been completed.

Conclusions

We will have more information regarding conclusions and next steps in Year 3.

References

No references needed in this report.

Appendices

No appendices needed in this report.