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TITLE: Probiotic (VSL#3) for Gulf War Illness

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14. ABSTRACT The overall objective of the study is to determine whether probiotic VSL#3® will improve 1) intestinal symptoms of Irritable Bowel Syndrome and 2) non-intestinal symptoms (fatigue, joint pain, insomnia, general stiffness and headache) associated with IBS. All of these symptoms are part of the Gulf War illness. The project was approved by Human Research Protection Office, Department of Defense in August 2013. We received the drug shipment from the manufacturer of VSL#3 in September 2013. We are in contact with the Lawrence Berkeley Laboratories to arrange for shipment of stool samples and microflora analysis. We screened our first participant in September 2013.					
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Introduction:

Gastroenteritis plays a major role in changing intestinal microflora. More than one third of Gulf War (GW) veterans report gastroenteritis during deployment and it is a risk factor for development of irritable bowel syndrome (IBS) after deployment. We also demonstrated that there is a strong association between IBS and extra-intestinal disorders (e.g. fatigue, joint pains, insomnia, generalized stiffness, and headache). This would suggest that IBS as well as extra-intestinal disorders in GW veterans have a unifying etiology. There is scientific evidence that probiotics by restoring normal gut flora improve symptoms of IBS. Probiotics have also been shown to improve arthritis and fatigue by changing fecal flora. This is the basis for our present protocol to study the effect of probiotics on GW illness.

Body:

During the last on year the following goals were accomplished:

- Study was approved by the University of Utah, Institutional Review Board in February 2013.
- Study was approved by the Human Research Protection Office at the United States Army Medical Research and Materiel command (USAMRMC), in August 2013.
- VSL Pharmaceuticals sent the drug shipment from Roma, Italy in September 2013. The drug was received at the VA pharmacy, Salt Lake City.
- First patient was enrolled in September 2013.
- Study co-investigator at Lawrence Berkeley Laboratories has been contacted for stool sample analysis.
- IRB approval for the study has been applied for, at the University of California, Berkeley.

Key Research Accomplishments.....

Nil.

Reportable Outcomes.....

Nil.

Conclusion:

This project has now been approved and is ready for enrollment.

The screening for this study has been started and two patients have been enrolled in the study.

References.....

Nil.

Appendices.....

Nil.