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PRINCIPAL INVESTIGATOR: Jordan H. Grafman, Ph.D.

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation
Rockville, Maryland 20852-1402

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13. ABSTRACT (Maximum 200 Words) Implementation of the Vietnam Head Injury Study Phase III (VHIS - PIII) has begun. By November 2003 all study staff had been hired, and underwent subsequent training to administer the battery of tests. By April 2004 we had received all the required protocol approvals and inter-agency cooperative agreements, and began testing subjects. To date, 28 head-injured subjects and 6 non-head injured control subjects have been assessed, and these data have been entered into the VHIS - Phase III computer database. Of those who were examined in Phase II, 320 head-injured subjects and 31 control subjects have agreed to further participation. We have publicized the study in both veteran, military and the national press, and are in the process of recruiting additional control subjects. The assessments have already identified four cases with significant undetected medical pathology.				
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Introduction

This report summarizes events for the period September 24, 2003 to September 23, 2004 in the implementation of the Vietnam Head Injury Study - Phase III: A 30-Year Post-Injury Follow-up Study, funded by the US Army Medical Research and Materiel Command, under grant no. DAMD17-01-1-0675.

Narrative

The implementation of the Vietnam Head Injury Study - Phase III (VHIS-P3) had previously been delayed during 2003 (See Annual Report, October 23rd 2003). The process of obtaining all necessary agreements continued in September 2003, and in October a Memorandum of Understanding (MOU) was executed with Walter Reed Army Medical Center to obtain the original VHIS Phase II CT brain scans for all subjects.

By November 2003 all study staff had been hired, and began training and final preparations for the administration of the battery of agreed tests. In January 2004, non-Department of Defense participants were granted Secretary of the Navy Designee Status to cover medical care associated with participation in the VHIS study. NNMC Command approval to conduct research (pending CRADA and CDA execution) was received on February 10th 2004. By March, the Confidentiality Disclosure Agreement (CDA) approval between NIH and NNMC was obtained, as was Cooperative Research and Development Agreement (CRADA) approval between NNMC and HJF. At this time NNMC also approved the Phase III consent forms. We received final Command approval on April 5th 2004, and began seeing subjects on April 27th 2004. We initially saw increasing numbers of subjects to test the tolerability of the battery, commencing with one, then two and then three subjects every 7-8 days.

From June 2nd, 2004 we have continued to test three subjects approximately every 7-10 days, with the battery taking 7 full days for each subject to complete. Data is being entered into the VHIS – Phase III computer database on a continual basis. In July final adjustments were made to the Analysis of Brain Lesions (ABLE) computer program to allow comprehensive examination of the CT brain scans taken in Phase III. In September the testing battery was reduced to 6 days, due to problems with subject fatigue. Roles of individual study staff were reviewed to afford the most time-effective schedule for subject testing.

Following acquisition of permission from the Human Subjects Research Review Board (HSRRB) to contact the 520 subjects who participated in Phase II, 320 head-injured subjects have stated they will attend for Phase III of the study. Of the original 80 control subjects without head injuries, 31 have responded positively. It was decided that further control subjects would be recruited through veteran publications. In May 2004, the control recruitment advertisement received approval by NNMC, and a website was created to publicize the VHIS. In June a press release was issued to 23 media outlets. The study was publicized in the "Pentagram" and in the NNMC base newspaper "The Journal", and in July in the Washington Times. In September the American Legion Magazine published the control recruitment advertisement, from which we have received a positive response from 12 potential control subjects.

During July 2004 there was a change in the NNMC Principal Investigator from Dr McKenna to Dr Hughes. At the same time, the NNMC semi annual report was submitted and approved, and a modified Statement of Work (SOW) was submitted and approved by USAMRMC.

To date 36 subjects have attended for testing: 28 head-injured subjects and 8 controls. All subjects have had blood samples taken for genetic analysis and all head-injured subjects have undergone a CT brain scan and EEG (if their individual physical condition allowed it). We have identified two cases of probable undetected epilepsy and two further cases with likely meningiomas.

We anticipate that we will be able to start initial analysis in January 2005, when we should have tested approximately 50 head-injured subjects and 10 controls. We are currently prioritizing recruitment of control subjects, so that we can expect to have assessed 50 control subjects by March 2005.

Key Research Accomplishments

- All necessary approvals received for commencement of VHIS Phase III.
- Refinement of the test battery, test software, forms, and task administrative procedures, including adjustment of testing roles of study staff.
- Training of all study staff in their required duties within the test battery.
- Gathering of data and maintenance of the VHIS – Phase III computer database.

Reportable Outcomes

CT scans performed: 27
EEGs performed: 28
Blood Samples collected: 36

Total participants seen: 36
Subjects: 28
Controls: 8