



31 JANUARY 2017

Dear Doctor:

Validation of a Cephalad Fluid Shift Countermeasure: Selection of Optimal Cuff Design Followed by ICP Measurements During Extended Cuff Application: A Study in Collaboration with the National Space Biomedical Research Institute (NSBRI) and National Aeronautics and Space Administration (NASA)

We are currently conducting a feasibility study to determine optimal thigh cuff design using a cephalad fluid shift protocol in patients who have an intraventricular catheter (such as Ommaya reservoir) placed for the delivery of central nervous system chemotherapy or for diagnosing potential elevation of ICP.

This study is in collaboration with Dr. Brandon Macias, scientist from NSBRI who is testing a device that will prevent visual impairment and intracranial pressure (VIIP) syndrome in astronauts involved in long duration space flights on the International Space Station. The current study explores a number of physiologic variables that may impact vision changes that have been reported in more than half of American astronauts after long duration space flights.

Key Inclusion Criteria:

1. Male or female, 18-65 years old
2. Willing and able to provide informed consent
3. Patients who have an intraventricular catheter placed for the delivery of central nervous system chemotherapy or for diagnosing potential elevation of ICP and monitoring its progression as part of standard medical care
4. KPS \geq 70
5. For subjects on active anti-cancer (intra-thecal or IV) therapy, must be at least 2 weeks since last treatment; oral therapy is permitted

Key Exclusion Criteria:

1. Screening ICP $>$ 20 mmHg that cannot be clinically stabilized
2. Pregnant
3. Existing cardiovascular disease, diabetes, syncope, ocular disease that, in the opinion of the investigator, may confound the study results
4. Uncontrolled neurological symptoms such as headache, nausea or vomiting that will limit the subject's ability to participate in the study
5. Injury, trauma, venous thromboembolism, peripheral arterial disease or any condition that
6. will prevent the subject from tolerating the application of a thigh cuff



If you are interested in hearing more about the study and might consider referring potential eligible patients, please contact our study coordinator, Najee Boucher at (310) 582-7460 or me at (310) 829-8265.

With your permission, we will contact the patient to review the study with them after you have broached the study with them, and, if the patient chooses to participate, we will obtain informed consent. In referring a patient to us, ***please be assured that our involvement will be strictly study-related.***

Please feel free to contact either myself or my staff for additional information or if you have any questions.

Best regards,

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