Early non-invasive detection of progression of mass effect from unilateral brain lesions

NCT04745884

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IRB Minimal Risk Protocol Template

Note: If this study establishes a human specimen repository (biobank) for research purposes, do not use this template. Use the Mayo Clinic Human Specimen Repository Protocol Template found on the IRB home page under Forms and Procedures at http://intranet.mayo.edu/charlie/irb/

First-time Use: Use this template to describe your study for a new IRB submission.

1. Complete the questions that apply to your study.
2. Save an electronic copy of this protocol for future revisions.
3. When completing your IRBe application, you will be asked to upload this document to the protocol section.

Modification: To modify this document after your study has been approved:

1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
3. Revise the protocol template to reflect the modification points , save the template to your files
4. Create an IRBe Modification for the study and upload the revised protocol template.

General Study Information

Principal Investigator: Alejandro Rabinstein, MD

Study Title: Early non-invasive detection of progression of mass effect from unilateral brain lesions

Protocol version number and date: v2.0, 06Jan2021

Research Question and Aims

Hypothesis:
Noninvasive monitoring of intracranial pressure curve may recognize progression of mass effect from non-traumatic hemispheric brain lesions before clinical changes become manifest and therefore guide the timing of repeat imaging.

Aims, purpose, or objectives:

1. To determine if the Braincare monitor can identify progression of mass effect from non-traumatic hemispheric brain lesions through continuous analysis of the ICP waveform and comparison of changes in ICP waveform from side to side.
2. To evaluate if changes in ICP curve indicative of progression of mass effect occur earlier than clinical changes that would routinely lead to repeat brain imaging.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):

Hemispheric brain lesions with mass effect can be life-threatening. These mass lesions can cause tissue compression and even brain herniation without substantially rise in the global intracranial pressure. This is the case because these focal lesions produce pressure gradients contrary to diffuse lesions that result in global exhaustion of intracranial compliance. As a consequence of this phenomenon, intracranial pressure monitoring via intraparenchymal or intraventricular catheters may fail to recognize progressive brain herniation from hemispheric mass lesions (1,2). While serial neurological and radiological examinations and brain are useful, these measures are neither continuous nor sufficiently sensitive. Therefore, having a tool that can recognize progression of mass effect through continuous monitoring at the bedside, particularly if noninvasive, would be extremely helpful. Such a tool would be feeling a major gap in clinical practice and could have the potential to have major practical applications.

Study Design and Methods

Methods:

Pilot study of 10-20 adult patients with non-traumatic hemispheric brain lesions deemed at risk for progression of mass effect and possible subfalcine and/or uncal herniation who are admitted the Neuroscience ICU for serial neurological monitoring and whose care is not expected to include immediate surgical decompression. Invasive ICP monitoring will not be required for enrollment in the study because it is currently not considered standard of care for non-traumatic hemispheric brain lesions (3,4). After obtaining consent from the patient of surrogate, enrolled patients will undergo bilateral monitoring of ICP with the Braincare device. In addition to the analysis of the ICP waveform, we will collect information on serial neurological and radiological examinations and any treatments administered for brain edema.

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 20

Subject population (children, adults, groups): Adult patients 18 years and older who are admitted to the Neuroscience ICU with a diagnosis of Hemispheric brain lesions.

Inclusion Criteria:

- Adult patients with non-traumatic hemispheric brain lesions deemed at risk for progression of mass effect and possible subfalcine and/or uncal herniation
- Patients admitted the Neuroscience ICU for serial neurological monitoring
- Patients whose care is not expected to include immediate surgical decompression

Exclusion Criteria:

- Patients under the age of 18

- Patients who are unable to provide consent due to neurologic deficit and does not have a surrogate decision maker available to provide consent.
- Known or suspected Pregnancy
- Adults with cranial defects or that have undergone crainiectomy

Biospecimens

Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

Prospective collection of biological specimens other than blood: _____

Review of medical records, images, specimens

Check all that apply (data includes medical records, images, specimens).

☐ Only data that exists before the IRB submission date will be collected.

Date Range for Specimens and/or Review of Medical Records:
Examples: *01/01/1999 through 12/31/2015*, or all records through *mm/dd/yyyy*.

Note: The Date Range must include the period for collection of baseline data, as well as follow-up data, if applicable.

☒ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.

- The study plans to collect data that occurs during the subject's hospital stay in the Neurosciences ICU. We will use the data that is collected from the non-invasive BrainCare device that will be applied to the patients who agree to provide informed consent for study participation.

☐ The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement:

Data Analysis Plan:

Endpoints

Primary: To determine if the Braincare monitor can identify progression of mass effect from non-traumatic hemispheric brain lesions through continuous analysis of the ICP waveform and comparison of changes in ICP waveform from side to side.

Secondary: To evaluate if changes in ICP curve indicative of progression of mass effect occur earlier than clinical changes that would routinely lead to repeat brain imaging.