Motor Cortex Location Study

Note: Recruitment is completed for this study.

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ABOUT THE STUDY
Cerebral palsy affects an estimated 800,000 people in the United States. One of the most common neurologic deficits associated with cerebral palsy is a weakness on one side of the body (hemiparesis). Our research focuses on exploring interventions that have the potential to improve motor function for children with hemiparesis due to stroke.

Watch a video on the study >>

Non-invasive brain stimulation (NIBS) is a form of painless stimulation that has potential to improve movement. Determining the optimal location to apply non-invasive brain stimulation in the brain is critical to maximize the potential of the intervention. We can measure this location using a non-invasive brain stimulation test or by conventional means measuring head size and landmarks.

This study will investigate the potential differences in using those two measurements to determine the location for future placement of electrodes in studies applying non-invasive brain stimulation as a potential intervention aimed to improve the hand function for children with hemiparesis.
The data collected from typically developing participants will provide confirmation of measurements and baseline information to compare with the data collected from children with hemiparesis.

The hypothesis for this study is that in typically developing children, the conventional landmarks to determine the brain area that controls hand function will not differ from NIBS-guided assessments. In children with hemiparesis, however, those two locations will differ.

What is required to participate in this study?

This study involves one visit that will last about 90 minutes at the University of Minnesota in Minneapolis. (Click here for more details about the visit). Before the visit we will do a 15 minute phone screen and review the participant's medical history to determine eligibility. For children with hemiparesis we will also obtain medical records for a review by our study medical director.

We are including children ages 8-17 in this study.

For typically developing children to be included they cannot have any history of neurological injury.

Children with hemiparesis must meet the following criteria:

- Congenital hemiparesis confirmed by an MRI or CT report
- A diagnosis of having had a hemispheric stroke or periventricular leukomalacia
- No evidence of seizure activity within the last two years

Due to safety issues children may be excluded if they have one (or more) of the following: metabolic disorder; neoplasm; epilepsy; disorder of cellular migration and proliferation; acquired traumatic brain injury; expressive aphasia; pregnancy; indwelling metal or incompatible devices; botulinum toxin or phenol intramuscular block within one month preceding scheduled participation.

All participants will receive a $50 Visa gift card upon completion of their participation in the study.

PARTICIPATION TIMELINE

Pre-Visit (2-4 weeks):
Complete a 15-minute phone screen regarding participant's medical history.
Review materials and sign medical records release forms.
Study physician will review the medical records and determine eligibility for the study.
If eligible, the study coordinator will work with the family to schedule the visit.

Day of Visit (90 minutes):
- Arrive at Clinical & Translational Science Institute.
- Review and sign consent/assent forms.
- Measurement of blood pressure and heart rate.
- Complete three brief hand function/strength assessments.
- Complete a brief symptoms survey.
- Swim cap will be placed on head and distances measured with a tape measure and marked on swim cap.
- TMS testing of cortical excitability: brain stimulation will be applied to scalp over swimcap and motor response will be measured.
- Blood pressure and heart rate will be measured again.
- Another brief symptoms survey will be completed.
- Family will be asked to complete a short feedback survey regarding participation experience.

FREQUENTLY ASKED QUESTIONS

How will I benefit from participating?
All participants will receive a $50 Visa Gift Card upon completion of their participation in the study. The indirect benefit of participating in this study is that the information obtained will be helpful in the future for intervention studies in children with hemiparesis. Determining the optimal measurement to use when applying brain stimulation as an intervention can maximize the potential for improving motor outcomes and enhancing the quality of life for children diagnosed with hemiparesis. Research provides the foundation for future interventions that can be used in the clinics.

Does brain stimulation hurt?
The application of Transcranial Magnetic Stimulation (TMS) is non-invasive (meaning the stimulation device is placed on top of the scalp) and non-painful. Adjustments are made throughout the procedure to maximize subject comfort.

How long is the actual application of TMS?
A small series of stimulation pulses are given within a 10-minute timeframe.
What are the risks with this type of brain stimulation?
In addition to the medical history of each subject being reviewed by the study physician, the study has been designed to minimize the likelihood of the following events during TMS testing:

- Subjects who have experienced brain injury may have an increased risk of a TMS-induced seizure. Our procedure for managing the possible risk of a seizure includes presence in the area of a physician or nurse trained in seizure management; ready access to life support equipment (oxygen, suction, blood pressure monitor, CPR equipment); and access to antileptic drugs.
- The possibility exists for a temporary headache due to the TMS or the tight swim cap surrounding the head. Adjustments to the cap most commonly alleviate this symptom.
- There is a possible risk of hearing loss. Therefore earplugs are administered to each subject and the position of the earplug is monitored.
- Fainting is also a risk. We monitor blood pressure at the beginning and end of TMS testing and by applying the testing in a semi-reclined position.
- Lastly, the possibility exists for TMS-induced mania, dental pain, cognitive impairment, motor control impairment, temporary neck pain, temporary hearing impairment, and unknown effects on hormones. The effects of TMS on thinking, memory and mood in subjects with stroke are not known.

Can the subject's parent or legal guardian be in the room during the visit?
Absolutely! We encourage both the subject and family to ask questions about the procedures before, during, and after their participation.

LOCATION OF STUDY

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<tr>
<th>Clinical &amp; Translational Science Institute (CTSI)</th>
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<tbody>
<tr>
<td>Masonic Memorial Building</td>
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<tr>
<td>424 Harvard Street SE</td>
</tr>
<tr>
<td>Minneapolis, MN 55455</td>
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<tr>
<td>612-625-2874</td>
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From Highway I-94 take the Huron Boulevard exit and go north. Then,

- Left on Fulton Street SE
- Right on Oak Street SE

The Oak Street Parking Ramp will be two blocks down on the right. After parking, exit the ramp and go west on Delaware to Harvard Street. Take a left on Harvard Street. The Masonic building is on the right. We will meet you at the front entrance of the Masonic Building. We will then go to Room 243.
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