Headache and sleep disturbances after traumatic brain injury - a sham controlled repetitive transcranial magnetic stimulation study

A Data Management Plan created using DMPTuuli

Creator: Susanna Melkas

Affiliation: Other

Template: Academy of Finland

ORCID iD: 0000-0003-0564-9637

Project abstract:
Headache and sleep disturbances are major problems after traumatic brain injury. In 2018, 2200 brain injury patients were treated in Helsinki University Hospital (HUH). In this group of patients, incidence for severe drug-resistant and persistent headache is about 20 patients per year. Our main question is how to best harness the neuroplastic capacity of the human brain to treat this patient group. Our aim is to determine how medication-free neuromodulatory therapies such as repetitive transcranial magnetic stimulation (rTMS), which has shown promising results in decreasing pain and headache intensity, could be tailored for each individual patient. We also plan to explore the neural mechanisms behind the treatment effect. In other types of drug-resistant neuropathic pain, about 40-50% of the patients benefit from rTMS and similar effectiveness could be expected for patients with persistent headache. We will also study the treatment effect of rTMS on sleep disturbances and on glymphatic flow, which is a newly recognized brain-wide network that allows cerebrospinal fluid to clean brain parenchyma from harmful metabolic waste. To study the mechanisms of neuromodulatory treatment, close collaboration is needed between physicians, sleep researchers, and experts in brain imaging, signal analysis, and network modeling. Close collaboration between HUH, University of Helsinki, and Aalto University (Department of Neuroscience and Biomedical Engineering, NBE) will offer the needed expertise. Department of Clinical Neurophysiology in HUH will offer expertise in conducting neuromodulatory treatments; together with Department of Radiology (HUH) and NBE of Aalto University the treatment effect will be studied using brain imaging, signal analysis and neuronal network modeling. Treatment-related functional neuroplasticity will be measured with TMS-EEG, with which cortico-cortical signal propagation and neuronal activation levels can be measured. The newest MRI methods will be used to quantify treatment-related structural plasticity in white matter. The newly built MREG technology in HUH will be used in studies of glymphatic flow. Neurological outpatient clinic together with pain clinic in HUH offers the expertise in treating and studying headache and pain. Aalto University with its most advanced TMS technology in the world and cutting-edge expertise in diffusion imaging and signal analysis will guarantee the adequacy of the technical quality of the studies.

Last modified: 24-09-2019

Copyright information:
The above plan creator(s) have agreed that others may use as much of the text of this plan as they would like in their own plans, and customise it as necessary. You do not need to credit the creator(s) as the source of the language used, but using any of the plan's text does not imply that the creator(s) endorse, or have any relationship to, your project or proposal.
1. General description of data

A) data collected for this project: clinical data (.sav)
B) data produced as an outcome of the process: MRI images including magnetic resonance encephalography (MREG) (.jpeg)
C) previously collected existing data which is reused in this project: none
D) managerial documents and project deliverables (.doc)

- Analog material will be digitised in as high resolution as possible for accuracy.
- In all conversions, maintaining the original information content is ensured.

2. Ethical and legal compliance

Personal data will be processed fairly and lawfully. It will be obtained only for the specified and lawful purpose which is our research question, and it will not be further processed in any manner incompatible with this purpose. Personal data will be adequate, relevant and not excessive in relation to this purpose. Personal and sensitive information will be removed from the data before sharing it in order to ensure privacy protection. Personal data processed for our purpose shall not be kept longer than is necessary.

Data is owned by HUS Hospital area. IPR issue concerning copyright is managed according to HUS data policy and Academy of Finland data policy. Issues concerning patent are not relevant in our project.

3. Documentation and metadata

We will use descriptive metadata to enable identification, location and retrieval of information resources by users.

4. Storage and backup during the research project

We will store and back up our data in external hard drives. The PI is responsible for backup and recovery.

The researchers of our research group have access to pseudonymised data, and they are authorised to analyse it. Secured access is controlled by use of password.

5. Opening, publishing and archiving the data after the research project

At this point we are planning to make only part of our data openly available. This concerns demographic and clinical data. Advanced imaging data and other registrations require special analysing techniques and thus, open access would not be of benefit.
Data with long-term value will be archived in a locked space accessible by the research group only. It will be stored for 15 years after finishing the project.

6. Data management responsibilities and resources

- Data collector: all researchers
- Metadata generator: PI
- Data analyzer: all researchers
- Project director: PI
- Data model and/or database designer: hired expert help
- Computing staff responsible for backup and/or storage: hired expert help