What does participation in this research involve?

If you and your doctor think you may be eligible to participate, you will sign a consent to participate and your medical and epilepsy history will be reviewed. If you qualify, you will undergo additional study tests and those normal to prepare for surgery. You will be implanted with the device under general anaesthesia and will stay at the hospital overnight.

Once the device is turned on and you are provided the external pieces, it will begin recording EEG signals. You will be monitored by your study doctor by having at least three (3) follow-up visits, including two (2) video EEG monitoring visits (either in-clinic or with an ambulatory clinic) through six (6) months after your surgery. You may be followed by the study doctor for three (3) years after your surgery. Information on how you are doing and if you are having any problems will be collected the entire time you are in the study.

You can exit the study at anytime and still continue with normal care by your doctor.

Who to contact for more information?

Location for contact information sticker

23 April 2021 - v1.0

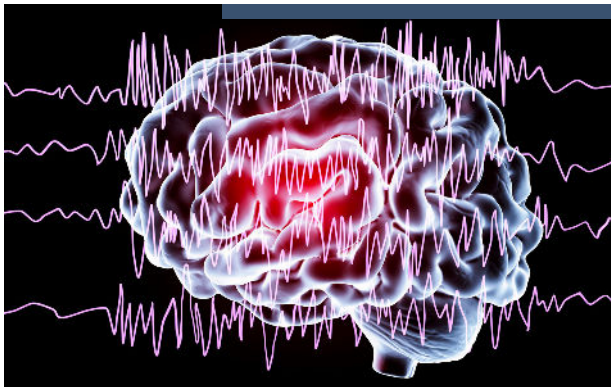
epiminder

Safety Assessment of a Sub-Scalp EEG Monitor

The Minder® system is an implantable medical device designed to collect EEG data from people with epilepsy.

This study investigates the Minder® system for long-term monitoring of EEG signals and safety in patients with focal or generalized epilepsy.

How the brain works



The brain works by very carefully controlling the individual activity of billions of nerves. The activity of the brain can be measured and observed by electro-encephalography (EEG).

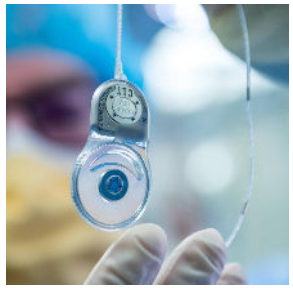
In epilepsy the brain activity is disrupted, and groups of nerves fire together in abnormal patterns, causing seizures. This abnormal activity can be detected via EEG recording and analysis.

There is currently no means of capturing continuous long-term (months or more) recordings of the EEG. The best solution currently offered is in-patient EEG or ambulatory recordings, which are each limited to days or weeks in duration and may not capture epileptic seizure events if they do not occur at this time

Purpose of the study

The purpose of this study is to test the long-term safety of the Minder® sub-scalp EEG monitoring system in patients with focal or generalised epilepsy.

The Minder® system



Implant

Behind-The-Ear

This new monitoring system is called the Minder® system and is made up of an implanted device that communicates to an external device called the Behind-The-Ear (BTE), mobile phone and secure cloud data. The Minder® system will record your EEG data and send it to a secure cloud using the mobile phone.

During the study, you will wear the BTE both day and night. You will also need to keep the phone (provided by Epiminder) nearby so that the data can be transmitted to the secure cloud. The data collected will then be analyzed and a report will be provided to your neurologist for review.

Am I eligible to participate?

You may be eligible to take part in this Safety Assessment of a Sub-Scalp EEG Monitor study if you have focal or generalised epilepsy.

Other key criteria that you should meet are:

- Between 18 and 75 years old
- Able to keep a seizure diary
- Able to complete regular study visits

You must not meet any of the following:

- Unstable medical conditions that require other care, procedures, or surgery
- Have neurostimulation device implanted for epilepsy or other condition
- Have had recent epilepsy surgery
- Are not eligible for device implantation surgery

There are other requirements and limitations for participating. Please check with your doctor to find out if you may qualify.

For information on the possible risks associated with implant surgery and the device, please speak with your study doctor.