MindRhythm Incorporated

Large Vessel Occlusion Validation Study EPISODE_LVO_MR1

Consent Form

Date of Document: November 10, 2022

NCT: Not yet assigned

TITLE:	HeadPulse Large Vessel Occlusion Validation Study
PROTOCOL NO.:	MRLVO001 WCG IRB Protocol #20222498
SPONSOR:	MindRhythm Incorporated
INVESTIGATOR:	Paul Lovoi, PhD Co-Founder and CTO 21710 Stevens Creek Boulevard Cupertino, CA 95014 United States
SUB-INVESTIGATOR:	Lisa Distenfield Director of Clinical Affairs Lisa.distenfield@mindrhythm.com
STUDY-RELATED PHONE NUMBER(S):	408-230-6396 954-552-4206 (24 hours)

In this consent form, "you" refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

We are asking you to participate in a research study. This form is designed to give you information about this study. We will describe this study and answer any of your questions.

What the study is about

The purpose of this research is to collect information about a type of signal that is found only in the brain; we call this the HeadPulse. This signal is a result of the normal movement of your brain during each beat of your heart. This movement within the brain can be disrupted or function differently when there is the presence of damage resulting from brain injury such as stroke or concussion.

The investigational Harmony 5000 device manufactured by MindRhythm has been tested in the pre-hospital environment with EMS teams to identify stroke type, but because LVO (the more debilitating large vessel occlusion stroke) is less common than non-LVO stroke, the sponsor, MindRhythm, wants to obtain additional recordings from patients with diagnosed LVO to better refine its algorithms that are used for identification of stroke type. Subjects will participate in the data collection process once subjects' CTA studies showing LVO stroke are obtained, and they are transferred to the angiography suite for thrombectomy. Recordings are performed in parallel to (at the same time as) your treatment so there will be no delay caused.

It is hoped that this information will help in the development of a device that could be used as part of the diagnosis of neurological conditions, including stroke.

Procedure

When you arrived at the hospital, the research team used the Harmony headset to monitor your brain. The research team was unable to ask permission at the time to conduct these recordings as you were unwell. The research team is requesting to use the recordings that were collected by the headset as well as simple information about your brain images, EMS stroke scale and basic demographics such as age and gender. For each recording, we placed the Harmony 5000 headset on your head as a signal was collected by the headset for a period of no more than three minutes at a time. Research support staff placed 3 ECG leads on your abdomen and chest and connected those leads to the Harmony headset. The headset was placed on your head and powered on. Once the headset was powered on, the research staff ensured you remained still for a period of 3 minutes while the research staff collected the HeadPulse data. The headset was removed from your head after the three minute period and that concluded your physical participation. Before you are discharged, on site research staff will meet with you to consent to use data collected during the recording as well as other deidentified information. The research staff will determine if you are able to consent or if a legally authorized representative is required to sign the consent form on your behalf. Once the consent document is signed, the research team will send data related to your condition (stroke type, stroke scale information, demographics, imaging reports) to the sponsor along with your HeadPulse information for analysis. Your name or any other information that could identify who you are will not be provided to the sponsor. If you or the legally authorized representative decline consent, data will be deleted.

Risks and discomforts

- Emotional risks: there are no expected emotional risks
- Social o*r economic risks: there are no expected social or economic risks*

- Physical risks:
    1. **Skin abrasion and hair pulling**: Mild skin abrasion or hair pulling could possibly occur during application or removal of the headband. These risks are considered mild and are minimized because the headband will be handled by the user.
    2. **Skin irritation**: ECG electrodes can possibly cause mild skin irritation when applied and then removed. Sensitive skin electrodes can be supplied if standard Red Dot electrodes cause irritation.
    3. **Infection:** It is possible, but not expected, that an infection could occur from wearing the headband. The headband has been decontaminated when supplied to you. If you will be placing it on your head more than once, the risk of infection is similar to reusing a comb.
    4. **Heat:** There is no expected risk of exposure to excessive heat as the headband contains electrical components that are very low voltage and do not transfer energy to the scalp. In the event that a component malfunctions the headband will immediately shut off.
    5. **Electric Shock:** There is no expected risk of exposure to electric shock. The headband is powered by a low voltage battery, and all circuitry will be covered by a disposable plastic sheath. The circuitry is designed to avoid the risk of electric shock.
- **Legal risks:** there are no expected legal risks nor expectation of activities that may require reporting to authorities.
- There are no other activities that will carry risks associated with this study
- There may be risks that are unknown at this time.

Benefits of Participating
There are no direct benefits to the patient in this study.

Information from this research is expected to benefit society in the future by improving an algorithm that will be used to triage patients in the prehospital setting who are suspected of having a stroke or have been concussed.

We believe better understanding of the pattern within the HeadPulse in both normal and ill patients (collected from other studies) will improve the diagnostic algorithm to 1) detect a major stroke from a small stroke and which hospital the patient should go to for the best treatment and 2) detect the presence of a concussion and the patient's recovery from concussion.

Alternative of Participating
This is not a treatment study. Your alternative is to not participate

Payment for participation
There is no compensation for participation in this study.

Audio/Video Recording
No audio or video recording of you will occur for the purposes of this research.

Privacy
Any HeadPulse data MindRhythm collects from the headset will be de-identified. Each participant will be assigned a unique study number that links all collected HeadPulse data. We will only collect your name and address during enrollment as part of the consenting process. These consent forms will be sealed and stored in accordance with HIPAA document requirements to protect your identity. We protect your information from disclosure to others to the extent required by law. We cannot promise complete privacy.

The FDA or other regulatory agency, the sponsor and IRB may look at all information recorded as a part of this study and medical records.

Data Sharing
Only de-identified data will be analyzed by personnel within MindRhythm, Inc.

De-identified data from this study may be shared with the research community at large to advance science and health. We will not collect or disseminate any information that could identify you.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Clinical Trial
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Time Commitment
The recording takes about 3 minutes of time.

Voluntary Participation
Your participation is voluntary, and you may refuse to have your data used at any time, discontinue at any time, or skip any questions or procedures that may make you feel uncomfortable. There will be no penalty to you.

Withdrawal by investigator, physician, sponsor, or participant
The investigators, or sponsor may stop the study at any time should they judge that it is in your best interest to do so. Additionally, you can be withdrawn from the study if you experience a study-related injury, you need additional or different medication/treatment. The sponsor may remove you from the study for various other administrative and medical reasons; they can do this without your consent. You may withdraw from the study at any time by making the request of your research team member. A letter of confirmation of withdrawal will be provided to you.

Financial Disclosure
Dr. Paul Lovoi, the investigator, is the founder and CTO and owns stock in the sponsor company. Lisa Distenfield, the sub-investigator, also owns stock in the sponsor company. Please feel free to ask any questions you may have about these disclosures.

If you have questions
The main researcher conducting this study is Dr. Paul Lovoi, a Co-Founder of MindRhythm Inc. Dr. Lovoi's telephone number is provided under the "Title" section on the first page of this document.

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them if you have questions, concerns, or complaints about the research study or questions about your rights as a research subject at 855-818-2289 or researchquestions@wcgirb.com.

You may also report your concerns or complaints anonymously to the Office for Human Research Protections online at HHS.gov.

You will be sent a copy of this form to keep for your records.

Statement of Consent

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted
- If assent is obtained, have the subject sign the consent form, unless the investigator determines that the subject is NOT capable of signing

Your signature documents your permission for you or the individual named below to take part in this research.

I have read the above information and have received answers to any questions I asked. I consent to take part in the study.

Your Signature_____ Date_____

Your Name (printed)_____

Signature of person obtaining consent_____ Date_____

Printed name of person obtaining consent_____

For participants unable to give Authorization, the following person is acting on behalf of the research participant

_____Date_____
Signature of subject's legally authorized representative

_____
Printed name of a subject's legally authorized representative

_____
Relationship to subject

_____Date_____
Signature of person obtaining consent

_____Date_____
Printed name of person obtaining consent

☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ _____

Signature of person obtaining assent Date

_____ _____

Signature of subject Date

This consent form will be kept by the researcher for at least five years beyond the end of the study.