THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

Participant Information Sheet/Consent Form

Study Title: Wireless HOME monitoring of Brain Pressure

Short Title: HOME Brain Pressure Study

Sponsor: University of Auckland, (UoA)
UoA Lead researcher Dr Sarah Jane Guild 0212969030

Study Site: Te Whatu Ora Te Toka Tumai (Auckland City Hospital)

Lead Study Doctor: Dr Peter Heppner, Neurosurgeon, Auckland City Hospital

Contact: Dr Peter Heppner 021893804

Ethics committee ref.: 2024 FULL 18327

This is the first clinical trial of the Kitea System in people with hydrocephalus.
You may not get any health benefit from the study device and there are potential risks of you having a device-related injury or illness.

Thank you for taking the time to discuss the **HOME Brain Pressure Study** and for considering whether you would like to be involved.

Please read this information carefully. This document is 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages. Ask questions about anything that you do not understand, or that you want to know more about.

Being involved in this research study is your choice. If you do not wish to take part, you do not have to and you do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. You will receive the best possible care whether you participate in the HOME Brain Pressure Study or not.

WHAT IS THE PURPOSE OF THE STUDY?

Hydrocephalus is treated by a neurosurgeon placing a shunt into a fluid space in the brain. Excess fluid drains away to the stomach. The issue is that shunts stop working. When this happens, the fluid builds up and pressure in the brain increases. Symptoms at this time are sometimes hard to distinguish from other things as they can include headaches, tiredness, vomiting etc. This means that people with hydrocephalus often go to hospital suspecting their shunt is failing. Anxiety and distress at this time is high.

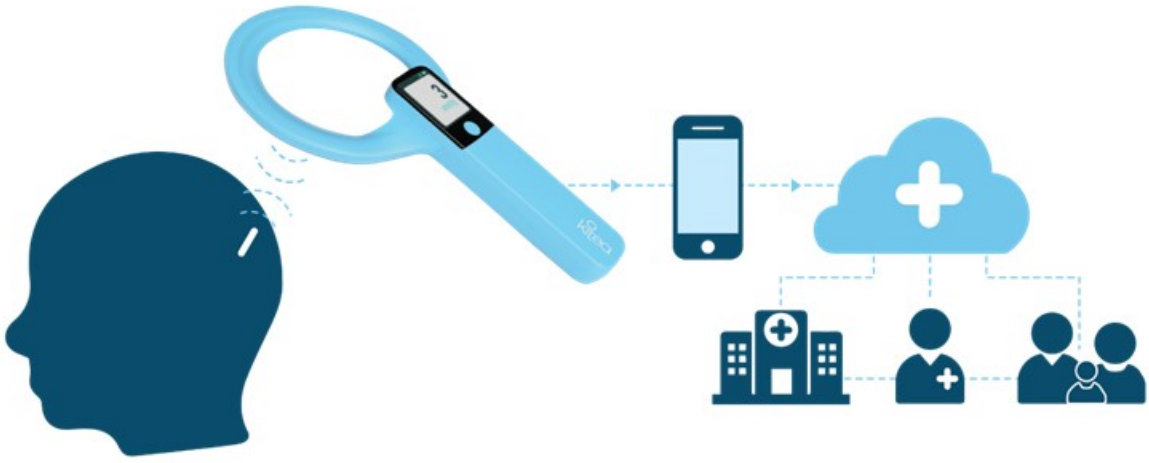
A University of Auckland research team have developed technology that measures pressure within the brain. We want to improve the lives of people with hydrocephalus by providing a tool for patients, families and doctors that measures the pressure in the brain. It is hoped that this system will reduce the number of times a person may go to hospital, reduce anxiety and provide certainty as to whether or not the shunt is failing.

The primary aim of the study is to show that people can take regular measurements of their brain pressure and that no safety issues occur with either the surgery or with taking measurements.

HOW IS THE STUDY DESIGNED?

This study is being conducted in Te Whatu Ora Te Toka Tumai (Auckland City Hospital) and will involve 10 adults and then 10 children. This is the first time the system will be used in humans.

You are scheduled to have a shunt placed in your brain by a neurosurgeon. If you decide to participate in this study, during your shunt surgery a pressure sensor will be placed in your brain alongside the shunt. The extra surgical time required to insert the pressure sensor, is expected to be between 15-30 minutes. It is important that you know that once the sensor is surgically implanted it will remain inside you either permanently or until your shunt is replaced.



The sensor contains no battery or moving parts and is 2 x 4 x 20 mm in size (about the same diameter as a shunt). It works by receiving power wirelessly from a special wand (see image above).

The sensor only measures your brain pressure when the wand is close (within 5cm) to your head. It cannot stimulate your brain. It cannot interact with the shunt. It does not release drugs. It cannot measure anything other than brain pressure.

You, and if you agree, members of your whānau will receive training in using the wand to take your brain pressure measurement.

When you are in hospital, after your surgery and when you are back home, we ask that you take regular sensor measurements using the wand for up to 3 months. When the wand is placed over the sensor it will record your brain pressure. The brain pressure number is shown on the wand and is wirelessly transferred to a special application (app) running on a phone (which we will provide to you). The app will allow you to add other symptoms you may have e.g., headache, extreme tiredness, nausea etc. This information will be transferred to your surgeon and to the study team via a web-based clinical portal.

The sensor can only be removed by a neurosurgeon and it is designed to enable you to take brain pressure measurements for many years. It is designed to be a permanent implant (like your shunt), but it can be removed if your shunt needs to be replaced or by a neurosurgeon at your request.

WHO CAN TAKE PART IN THE STUDY?

You have been invited to participate in this research as you are either having a shunt placed for the first time or having a shunt replaced in your brain to treat your hydrocephalus.

To participate in this study:

- You must be able to give informed consent and be able to use the equipment provided to you (wand and phone).
- You must be available to participate in regular follow-up clinical visits, e.g. you are not intending travelling overseas during the study period and you will be available to be contacted by a member of the study team.
- You must not have another serious illness that might make you prone to infection.
- You must not have another electronic implanted medical device, e.g. pacemaker, cochlear implant, implantable cardioverter defibrillator, deep brain stimulation device. This is to avoid the unlikely occurrence of the Wand interacting with these devices. The Kitea Sensor itself is inert and will not affect any nearby devices. If you or another member of your family have an electronic implanted device, it is unlikely to be a problem but please feel free to discuss this with the study team.
- You must not be likely to require radiation therapy.
- You must consent to the collection of brain pressure and symptom information.

There will be no change in your clinical care by taking part in this study. Apart from making regular brain pressure measurements there are no medications or other treatments. There are no restrictions to your lifestyle, other than overseas travel, by participating in the study.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You will be approached by a research staff member in the pre-admission clinic or in the hospital before your surgery. You will be asked to read this Patient Information Sheet/Consent Form and then provide your consent by signing the form. You will receive a copy of your signed PISCF to keep and a copy will be kept in your medical notes. A letter will be sent to your GP to let them know that you are participating in the Home Brain Pressure Study.

If you consent to participate, your anaesthetic, surgery and care after surgery will proceed as normal with an additional 15-30 minutes of surgery time for the sensor placement, training on using the wand and phone app to take brain pressure measurements and an extra 3 month visit to the study team.

There will be no change in your clinical care by taking part in this study. There are no extra scans other than those of standard clinical care post-shunt placement. Your regular post-surgical clinic visits will take place as normal.

After you have given your written consent to participate:

Before surgery:
We will ask you about your health and medical history. This will take a few minutes and can be answered with the study team, while you are waiting to go into surgery and during the follow-up phone calls. Our study team will also check your medical records. This information will be kept confidential.

In hospital after surgery:
After your surgery you will take sensor measurements each day.

You can take measurements more often if you want to make sure that you, and your family, understand how to take measurements and how to use the app works before you go home.

The study team will help you with this and show you and your family how to take these measurements.

At home and follow up:
When you leave hospital, you will take the Wand and phone with you.

Measurements: Each measurement will require about 5-7 minutes of your time. Each time you take a measurement you will need to sit quietly for about 5 minutes (this is the longest part). You may choose to read a book or watch TV etc. You will then hold the wand near your head, over the sensor, and will take a measurement by holding a button down for ~10 seconds. The Wand will beep to tell you the measurement is being taken. Another person can help in taking the measurement, but we expect that you will have no problem in taking a measurement yourself. After taking the measurement you will add any symptom and activity information into the app on the phone.

Day 1 to Day 14: You will take a brain pressure measurement every day for the first two weeks after your surgery. You can take the measurement at any time of the day.

A member of the study team will contact you daily, until you feel confident that you are accurately recording the measurements.

Day 15 to Day 90: You will take a measurement every two days for 3 months.

Exception: The only exception to this timetable is if you are feeling unwell with symptoms that might be related to your hydrocephalus. Then you would take an extra measurement.

A member of the study team will contact every two weeks to see if you are having any issues or questions with making measurements or using the app.

3 months (Day 90): There will be an additional neurosurgery clinical visit where we will ask you to complete a brief survey of your experiences this will include some questions on your ability to use the system, and also if there are any changes in how you think about your hydrocephalus, e.g., your anxiety level. There will also be a physical exam by the study doctor and a review of your symptoms during the study. This is expected to take 60 min. At that time, we will share with you the initial findings of the study and the next steps for the technology.
After 3 months: we hope that you will continue to make regular pressure readings. Any data collected using the app will continue to be available to the research team, even if collected after the 3-month study period ends. These data may be included with the research data in any future reports or publications.

If you come to hospital for any reason in the future the study team will be notified because we need to track any events that could be due to an issue with the sensor or system.

Phone App: On the app on the phone, you will see a diary of your brain pressure over time. Each time you take a reading you will be asked to insert any other symptoms you may have at that time such as headache, nausea etc. In this way a personal diary of your brain pressure and symptoms will be developed and may aid your doctor in determining if your shunt is working correctly. The study team will be able to access the information you enter into the app via the web-based clinical portal.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participation in any research study is **voluntary**. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage; however, the sensor will remain in place until your shunt is replaced.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

This is the first human study of this pressure sensor technology in the world. The pressure sensor is to be placed directly in your brain tissue near to the shunt at the same time as your shunt surgery. While the sensor is very small (2 x 4 x 20 mm) it will contact directly with brain tissue. The University of Auckland research team has undertaken extensive animal testing (in sheep for at least 6 months) and not identified any risks separate from the neurosurgical procedure to place the shunt. Should information of an adverse effect become known during the study you will be informed. The animal testing has shown that the sensor does not move within the brain over time, that the material the sensor is built from does not significantly irritate the brain, that the sensor is safe if you have an MRI or CT brain scan, or X-rays. Taking a brain pressure measurement with the wand does not cause any heating or change in brain function.

Testing by an independent laboratory has shown that a person with the Kitea sensor may be safely scanned in a 1.5 T or 3.0 T scanner. The images from an MRI scan of the brain area within 3cm of the Sensor may be distorted. If it is clinically important to view within area immediately surrounding the Sensor, and other imaging modalities (e.g. CT scan) are insufficient, a neurosurgeon may recommend the Kitea Sensor be removed.

There will be no change in your usual clinical care. Your brain pressure data will not be used by itself to alter your care; however, your neurosurgeon will be aware of the brain pressure measurements and may take this information into consideration with your symptoms if you come to hospital again.

If you have questions on the equipment provided e.g., app/phone or wand, the study team will be always available to answer them.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may not directly benefit from participating in this study as your brain pressure measurements will not be used to alter your clinical care. However, your neurosurgeon may take the brain pressure measurements into consideration with your symptoms in trying to determine if your shunt is performing correctly.

We hope that this study will contribute to the good of other people who live with hydrocephalus. We hope this tool will reduce the number of times a person may go to hospital, reduce anxiety, and provide certainty as to whether or not the shunt is failing. There are also benefits to wider New Zealand Aotearoa society through the successful development of this technology.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

If you choose to not participate in this study, your surgery will progress as planned and there will be no change in your care.

WILL ANY COSTS BE REIMBURSED?

You will be given a mobile phone that contains the app and contact details of the study team. The phone will come with a modest data plan and call allowance for 12 months. You will be able to keep the phone and wand after the study ends.

We will reimburse your transport costs when you come to the hospital for your 3-month visit.

At the end of the study period (3 months) we offer you a koha as a thank you for taking part.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

If the sensor was to stop working it is unlikely to cause a problem in your brain.

WHAT WILL HAPPEN TO MY INFORMATION?

Throughout this study, the study doctors/researchers, nurses and other Te Whatu Ora Te Toka Tumai (Auckland City Hospital) staff will record information about you and your study participation. This includes identifiable information such as your name, NHI (hospital) number, sex, date of birth and clinical aspects around your hydrocephalus such as the type of shunt and placement site. The results of brain pressure measurements and the symptoms you enter into the app will also be recorded. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). There may be situations where the following groups may have access to your identifiable information:

Te Whatu Ora Te Toka Tumai (Auckland City Hospital) staff and study team (to complete study assessments).

The University of Auckland members of the study team (to complete study assessments).

With your consent, your GP will be notified of your participation in this study.

The University of Auckland independent study monitors will see your information to make sure the study is being run properly and that the data collected is accurate.

The University of Auckland and its representatives will need to see your information if you make a compensation claim for study-related injury. Identifiable information is required to assess your claim.

If the study or site is audited the ethics committee, or government agencies from New Zealand will need to see your information. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.

Your usual doctor (your GP or specialist) will be notified if a brain pressure measurement gives an unexpected result that could be important for your health or well-being. This allows appropriate follow-up to be arranged.

Rarely, it may be necessary for the study doctor to share your information with other people – for example, if there is a serious threat to the life or health of you or another person, OR if the information is required in certain legal situations.

De-identified (Coded) Information

If you agree to participate in this research project, you will be enrolled onto the study and given a study number. All your gathered health information will be stored in 'coded' format,

which means it will be stored against this study number not against your name. A confidential enrolment log that links your name and the study number will be kept in a secure location at Auckland Hospital. No information that identifies you will be used in any reports or presentations and any study information sent to the University of Auckland, except for the study investigators. Instead, you will be identified by a code.

The following groups may have access to your coded information:

The study team in the Te Whatu Ora Te Toka Tumai (Auckland City Hospital), University of Auckland and Kitea Health Ltd, for the purposes of this study.

Regulatory or other governmental agencies worldwide.

The results of the study may be published in a journal with international readership and available to mainstream media who may wish to report on the study. or presented at a conference, results will not be in a form that would identify you.

Future Research Using Your Information.

If you consent to this study, your coded information may be used for future research related to hydrocephalus.

The results may be analysed again at a later date or may be combined with the data of other studies. Kitea Health Ltd and people who work with Kitea Health Ltd may use the results of this study to understand the disease better or to review the safety or effectiveness of the study sensor, or for other research purposes. This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your de-identifiable information may be shared widely with other researchers or companies.

You will not get reports or other information about any / some research that is done using your de-identifiable coded information.

Your de-identified information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information or withdraw consent for its use once your information has been shared for future research.

Security and Storage of Your Information.

Your identifiable information will be held at Te Whatu Ora Te Toka Tumai (Auckland City Hospital) during the study. After the study is completed, it is transferred to a secure archiving site and stored for at least 10 years or for 10 years after you turn 16, then destroyed. However, Kitea Health may store the brain pressure measurements and other information entered into the app indefinitely, on secure servers, as above, for future research. This information will be available to your neurosurgeon for as long as you are using the system.

Your coded de-identifiable information will be entered into electronic case report forms and stored on a secure server. De-identified information will be kept indefinitely by the UoA study team in a secure, cloud-based storage. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job, or obtain health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the study team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask Peter Heppner (Study doctor) or Sarah-Jane Guild (Lead researcher).

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the study team.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. You will still be able to keep the phone and receive the koha.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to Kitea Health Ltd and the University of Auckland. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come.

Use of New Technologies (e.g. Artificial Intelligence, Health Apps).

The use of the app on the phone is a mandatory component of study participation.

The use of the app involves 2 factor authorisation and subsequently a password to access the app.

The initial use of the app will require you to include identifiable information such as your name, NHI number, sex, date of birth and clinical aspects around your hydrocephalus, e.g. type of shunt and placement site. Some of this information will be included in conjunction with the surgeon placing your shunt.

The information you include in the app will be available to a dedicated clinical portal that the researchers and surgeon will be able to access. This clinical portal will provide identifiable information about you and may be collated with other results obtained in hospital such as MRI or CT scans.

When you sign into the app for the first time you will consent to the use of the data (identifiable information) as described above.

There are no costs to you in using the app.

Information provided in the app will be stored in the cloud utilising 3rd parties. These parties provide and maintain the app and the web-based clinical portal that allows the clinical team to access the data.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Te Toka Tumai – Auckland Māori Research Review Committee about the collection, ownership, and use of study data.

- We have engaged with members of a number of iwi during development of this study.
- We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you decide to withdraw from the study you can let any of the study team know. Withdrawing from the study will not change your clinical care.

You will need to talk with Peter Heppner (lead doctor) about your options with the implanted sensor. The sensor cannot be removed without brain surgery and thus the ideal time for the sensor to be removed is at the time of your next shunt revision.

If you withdraw from the study, data will no longer be collected from the app, even if you continue to use the wand to make brain pressure measurements for your own understanding of your condition.

The data previously collected in the study will remain available for analysis. This is to protect the integrity of the study.

CAN I FIND OUT THE RESULTS OF THE STUDY?

We will provide you with a summary of the study results, within 18 months after the study is completed, if you have ticked that option in the consent form below.

The study will be registered in NZ with MedSafe
www.medsafe.govt.nz/regulatory/DevicesNew/3WAND.asp
and in the US at www.clinicaltrials.gov.

WHO IS FUNDING THE STUDY?

This study is funded by the Health Research Council of NZ.

This study is being conducted by the study team involving members of the Department of Neurosurgery and Neurology, Te Whatu Ora Te Toka Tumai (Auckland City Hospital) and the Auckland Bioengineering Institute, University of Auckland.

Components of the system (the Wand and the App) are provided by the commercial entity Kitea Health Ltd.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northen A HDEC has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Sarah-Jane Guild,
Department Physiology and Bioengineering Institute,
University of Auckland
Ph 021 2969030 or s.guild@auckland.ac.nz

Dr Peter Heppner, Neurosurgeon,
Department of Neurosurgery,
Te Whatu Ora Te Toka Tumai (Auckland City Hospital),
Ph 021893804 or pheppner@adhb.govt.nz

Study Nurse / Coordinator: **Davina McAllister** Ph 0274891940

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

If you require Māori cultural support, contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext. 42324

You can also contact the health and disability ethics committee (HDEC) that approved this study by email hdecs@moh.govt.nz

Please feel free to contact any of the study team if you have any questions about this study.

Thank you in advance for your help with this study.

Consent Form

Study Title: Wireless HOME monitoring of Brain Pressure - HOME Brain Pressure Study

Short Title: HOME Brain Pressure Study

Sponsor: University of Auckland, (UoA)
UoA Lead researcher Dr Sarah Jane Guild 0212969030

Study Site: Te Whatu Ora Te Toka Tumai (Auckland City Hospital)

Lead Study Doctor: Dr Peter Heppner, Neurosurgeon, Auckland City Hospital

Contact: Dr Peter Heppner 021893804

Ethics committee ref.:

Declaration by Participant

I have read the Participant Information Sheet or have had it read to me in a language that I understand, for volunteers taking part in the Home Brain Pressure Study.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whānau/ family support, or a friend to help me ask questions and to understand the study.

I am satisfied with the answers I have been given regarding the study and I understand that I will be given a copy of this consent form and information sheet to keep.

I freely agree to participate in this study as described and I understand that I may withdraw from the study at any time without this affecting my medical care.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I consent to the research staff collecting and processing my information, including information about my health.

I consent to my information being sent overseas.

I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material which could identify me personally will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study. Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of study team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Thank you for offering your consent to participate. A copy of the information sheet and consent form will be provided to you and copies filed in your medical notes.