|  |  |  |
| --- | --- | --- |
| **Participant Information Sheet**   **[Feasible, safety and utility of Endoscopic ultrasound-guided PPG measurement (EUS-PPGM) in patients undergoing liver resection and major intra-abdominal surgeries. ]** | |  |
| Formal Study title: | Feasible, safety and utility of Endoscopic ultrasound-guided PPG measurement (EUS-PPGM) in patients undergoing liver resection and major intra-abdominal surgeries. | |
| Lead [Researcher / Study Doctor]: | Dr Frank Weilert | |
| Study Site: | Waikato Hospital | |
| Ethics committee ref.: | **<<<<<<<<<<<TBC>>>>>>>>>>>>>** | |
|  |  |  |

|  |
| --- |
| **Voluntary Participation and Withdrawal From This Study** |

You are invited to take part in this study because you have been diagnosed with liver disease and your specialist has recommended you to undergo abdominal surgery to remove cancer in the liver or liver transplantation.

This study will be looking at whether you have evidence of high pressure in one the major blood vessels supplying blood to the liver by measuring the pressure difference between the vessels.

This Participant Information Sheet will help you to decide if you would like to take part. It explains why we are doing the study, what your participation would involve, what are the benefits and risks might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide, you may want to discuss with other people, such as whānau, friends, or healthcare providers.

This Participant Information Sheet/Consent Form informs you about the tests and procedures that will be done during the study. Your participation is voluntary. It is not part of your regular health care. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it will not affect the care you receive. You will receive the best possible care whether or not you take part. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

If you agree to take part and are deemed eligible, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

By signing it you are telling us that you:

• Understand what you have read

• Consent to have the tests and procedures that are described within this document.

• Consent to the use of your personal and health information as described.

This document is 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## **What is the purpose of the study?**

Portal hypertension is an abnormal increase in pressure around the liver, i.e. high blood pressure.

The purpose of this study is to look at the use of an advanced ultrasound device before surgery to check for the presence of high blood pressure around the liver in comparison to the standard approach in Waikato Hospital (Transjugular approach). Using an ultrasound device (EUS) to measure the pressure is a newer and less invasive technique. This advanced technique has been performed successfully in 10 patients by specialists in our Endoscopy unit in Waikato Hospital. This technique has also been validated worldwide.

The degree of high blood pressure will provide your surgeon with important information to assess the risk of the surgery so that you and your whānau can make an informed decision together. If you are found to have severe high blood pressure around the liver, your surgeon may recommend not going ahead with the surgery given that it is associated with higher surgical risk. Your GP will be notified of the result and outcome.

**Pressure measurement via the neck - Transjugular Approach**

This is the *current gold standard* way of estimating the blood pressure around the liver.

The measurement will be obtained by puncturing the neck vessel by a small needle and assessing the pressure with a pressure meter.

The disadvantages of this technique include the need for an invasive procedure; exposure to radiation from X-Rays done as part of the procedure and the requirement for a skilled radiologist.

**Ultrasound guided pressure measurement via the mouth (EUS-PPGM) Approach**

This is a newer technique, involves a less invasive procedure, and measures the pressure around the liver directly.

The ultrasound device will be inserted into the stomach via the mouth. A very small needle will be used to puncture the stomach and liver to assess the blood pressure with a pressure meter.

This method has been tested in animal and human studies. There are two separate research studies and showed a 100% technical success rate, with no adverse events of infection or bleeding.

With this technique, it requires no iodinated contrast or radiation exposure from X-Rays, and allows for direct measurement which is likely to be more accurate.

|  |
| --- |
| **How is the study designed?** |

We are aiming to recruit up to 40 patients to participate in this study. This is the first study looking at this in New Zealand. There is currently a similar study being conducted at the Royal Adelaide Hospital, Australia.

|  |
| --- |
| **Who can take part in the study?** |

You are being approached about this study because you have been diagnosed with cancer in your liver and your specialist has recommended that you undergo surgery to remove cancer in your liver or liver transplantation. You will be reviewed in the General Surgical outpatient clinic to discuss the pressure finding and treatment options.

You may be excluded from the study if you have significant abnormal blood results, having significant fluid in the abdomen, severe liver scarring, or if you have large blood vessels in your oesophagus or stomach that stop our device reaching your liver.

Even though the pressure measurement via the neck is the gold standard way to measure high pressure around the liver, it may or may not be done routinely if you decide not to take part in this study.

## **What will my participation in the study involve?**

To take part in this study, you need to come to our endoscopy unit (Reception J, Level 3 in the Waiora building) for a procedure to examine the upper part of your digestive tract with the ultrasound device. It will be done by a specialist experienced in the procedure. The Endoscopist will explain the procedure to you and your whānau prior to the procedure and answer any questions or concerns. You will also be invited to come to the Radiology department (Reception J, Level 3 in the Waiora building) for the pressure measurement via the neck vessel within 7 days prior to surgery. It will be performed by a radiologist experienced with the procedure. The radiologist will explain the procedure to you and your whānau prior to the procedure and answer any questions or concerns.

These procedures are generally done as a day-case, however, if you experience any adverse reactions, you may be asked to stay in the hospital until you recover from this.

No samples such as blood, urine, tissue will be collected for this study*.*

You will be follow-up 24 hours, 7 days and 12 weeks after the procedures with either a clinic review or a phone call.

**Cultural consideration**

We understand that Māori may have cultural considerations when participating in any study, we acknowledge the experience and knowledge shared by participants is a taonga; data collected is treated as invaluable and will be treated with respect. Further, Waikato hospital respects the importance of tikanga so please inform us if you wish to have whānau support present.

## **What are the possible risks of this study?**

**Pressure measurement via the neck - Transjugular Approach**

It is considered a safe procedure.

Major complications are infrequent and include:

- Bleeding

- Hematoma (bruise) at the puncture site

More rarely:

- Arteriovenous fistulae (connection between an artery and a vein)

- Horner syndrome (An interruption of nerve supply from the brain to the face and eye, on one side of the body)

- Abnormal heart rhythms (recovery without any treatment is expected in more than 90% of occasions).

o The use of ultrasound guidance for the puncture reduces these complications.

- Clot in the vein in approximately 0.5% of cases.

**Ultrasound guided pressure measurement via the mouth (EUS-PPGM) Approach**

It is considered a safe procedure.

Serious complications occur in **less than 1%** of cases including:

* Bleeding (similar rates to TJ-HVPG). Accessing the portal vein will carry no increased risk of bleeding compared to Fine Needle Aspirations, which are considered a standard procedure.
* Perforation – a hole that develops through the wall of your digestive tract.
* Inflammation of the pancreas.
* Infection.

In the unlikely event of an adverse event or side effect that happens after these procedures, there is a potential risk of delay of surgery as a result. If a delay in surgery were to occur which could possibly be related to the procedures of the study, we would stop recruiting to the study until this had been fully investigated.

You will be observed carefully for signs and symptoms of possible adverse events, in particular bleeding. If you experience any unusual symptoms or adverse events, please inform your doctor immediately.

All adverse events reported by yourself or observed by the investigators or medical staff will be recorded and reported to the principal investigator.

Follow-up of adverse events:

All adverse events will be followed until they have recovered, or until a stable situation has been reached. Follow up or further review may be recommended by the study team.

Surgery

Your surgery is part of your normal treatment and therefore you will be informed regarding this as part of your normal care.

|  |
| --- |
| **What are the possible benefits of this study?** |

By taking part in this study, you will help us to confirm that the ultrasound approach is as accurate as the current gold standard approach.

Knowing the degree of high blood pressure around the liver will provide your surgeon with important information to assess the risk of the surgery so that you and your whānau can make an informed decision. You participation in this study may help other cancer patients in the future.

|  |
| --- |
| **What are the alternatives to taking part?** |

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. You are free to withdraw from the study at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Waikato Hospital.

Instead of taking part in this study, you may continue with your standard care, which would be to continue with surgery as planned.

Your study doctor will discuss these options with you before you decide whether or not to take part in this research study. You can also discuss the options with your whānau, friends, or other healthcare providers.

## **Will any costs be reimbursed?**

**Who pays for the tests?**

There will be no cost to you for participating in this study.

Any part of the study that is part of your normal care, such as your surgery, will be covered as usual if you are entitled to receive treatment in New Zealand.

**Will I be paid?**

You will not be paid for taking part in this study.

## **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.

## **What will happen to my information?**

**Privacy and confidentiality**

The study staff will manage your personal data (information about you) in compliance with the laws governing the protection and privacy of personal information under New Zealand privacy legislation and as described in this Consent Form. By signing the Consent Form, you consent to the study staff collecting and using personal information about you for the research study. Any information obtained in connection with this research study that can identify you will remain confidential.

Although efforts will be made to protect your privacy, absolute 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 health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Your coded information may be sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information.

**What personal data will the study staff collect?**

If you join this study, the study doctor/staff will collect and use your personal data to do the research. 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. This personal data may include, among other items, your name, address, date of birth, and health data (information about your health). Your name, address and phone number will be on the demographics page for the study so we can identify you correctly at visits and contact you. This information may be used to obtain health records but is not supplied to anyone overseas.

Sensitive data such as racial or ethnic origin will also be collected, as it is necessary for the evaluation of the study results.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the Consent Form, you agree to the study team accessing health records if they are relevant and limited to what is necessary to your participation in this research study. Information about your participation in this research study may be recorded in your health records.

**Who will have access to your personal data?**

Your personal data may be stored in paper files and electronic databases which have limited access. The study doctor/staff will have access to these paper files and databases. Other people may also need direct access to this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements.

Monitor(s), auditor(s), ethics committee(s), regulatory authorities, radiology department, gastroenterology department and Waikato Hospital will be granted direct access to your original medical records for verification of clinical study procedures and/or data, to process and report your screening and safety tests, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. In addition, if a study test gives an unexpected result that could be important for your health, this would allow your usual doctor to arrange appropriate follow-up. Moreover, if you make a compensation claim for study-related injury, identifiable information is required in order to assess your claim.

Rarely, it may be necessary to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations. By signing this informed Consent Form, you authorise such access.

Records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your identity will remain confidential.

**How will your personal data be protected?**

To make sure your personal information is kept confidential, your personal data will be labelled with your participant number (“your coded data”). No direct personal identifiers such as your name, initials or date of birth are included in your coded data. Identifiable data will not be included in any report generated by the researcher, instead, you will be identified by a code.

The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed. This means it will be re-identifiable by Waikato Hospital only.

**Sharing of your coded data**

The coded information may be used for future research related to portal pressure gradient in liver cancer or liver disease. This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers but always in a coded or de-identified format. Your coded information may also be added to information from other studies to form much larger sets of data that can be used in future research.

**How long will my personal data be stored?**

Records containing your personal data will be retained for a period of at least 15 years at Waikato Hospital premises and/or in secure offsite storage at the end of the study.

**Right to access information collected during the study**

In accordance with relevant New Zealand privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information or any questions about the collection and use of information about you.

**What happens after the study or if I change my mind?**

**Can I change my mind about participating?**

You can agree to be in the study now and change your mind at any time and for any reason. Please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing, such as follow up visits.

Any information collected before your withdrawal from the study may continue to be used and included in the study as it may not be possible to remove this information once it has been de-identified or coded to protect your identity. However, you may ask for your information to be deleted as much as possible when you withdraw as long as the study analyses have not been undertaken.

**Can the study staff remove me from the study?**

The study doctor have the right to remove you from the study at any time, with or without your agreement.

These decisions will be made if:

• It is in your best medical interest to stop

• You do not follow the study staff’s instructions

• The study is cancelled

• You no longer meet the eligibility criteria

The study doctor/staff will discuss with you the reasons for removing you from the study, other treatment or research options, and plans to follow up with you for side effects, if needed.

**Can the study be stopped unexpectedly?**

This research study may be stopped unexpectedly for a variety of reasons. This could include unacceptable side effects, insufficient information or any other reason that means it would be unacceptable to continue. This decision will be made by an independent group of specialists and you will be informed of the outcome of their decisions if this happens.

|  |
| --- |
| **Can I find out the results of the study?** |

After all study participants have completed the study (which may be some time after you have completed your participation in the study), we will analyse the data and offer you a summary of the study results that are understandable to the general public. The summary will not include individual results or information that can identify you or any other study participant.

|  |
| --- |
| **Who is funding the study?** |

This study does not receive any funding. If knowledge acquired through this research leads to discoveries that are of commercial value, the study doctors or their institutions, there will be no financial benefit or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information to you or your family. The rights to these will all belong to Waikato Hospital.

|  |
| --- |
| **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 [insert Committee name- TBA] 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:

*Dr Stephanie Yung (Gastroenterology Fellow)*

*Telephone number: 078398899*

*Email: stephanie.yung@waikatodhb.health.nz*

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

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@advocacy.org.nz

Website: https://www.advocacy.org.nz/

If you require Māori cultural support, talk to your whānau in the first instance.

Te Puna Oranga are available for cultural support throughout the duration of the trial. A member of Te Puna Oranga can be contacted at Waikato Hospital.

Phone: 07 834 3644. extension 97844

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC

Email: [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)

|  |  |
| --- | --- |
| **Consent Form**   **Feasible, safety and utility of Endoscopic ultrasound-guided PPG measurement (EUS-PPGM) in patients undergoing liver resection and major intra-abdominal surgeries** | *Your letterhead* |

**Please let study staff know if you require an interpreter.**

**Please tick to indicate you consent to the following**

***Please only include yes/no boxes if the statement is truly optional (i.e. that a person could still participate if they answer no).***

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. |  |  |
| 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 understand the study. |  |  |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |  |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |  |  |
| I consent to the research staff collecting and processing my information, including information about my health. |  |  |
| I consent to my information being sent overseas. |  | |
| 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. | Yes o | No o |
| 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 understand that I can request a summary of the results from the study.. | Yes o | No o |
|  |  |  |
|  |  |  |

**Was an Interpreter was used? Yes No**

Interpreter’s name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Language of the participant that was supported:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_(Date DD/MMM/YYYY)

**Declaration by participant:**

I hereby consent to take part in this study.

|  |  |
| --- | --- |
| Participant’s name: | |
| Signature: | Date: |

**Declaration by member of research 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: |