**Patient Information Sheet**

**Near infra-red imaging of the microvasculature in comparison with resin casting of amputated limbs**

**Introduction**

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask.

Thank you for taking the time to consider our study.

**Study purpose**

This study involves near-infra red imaging to determine how well we can see small blood vessels. After we image a limb, we will make a resin map and compare this map with what we have imaged with the near-infrared camera. We hope that the imaging will show us a clear picture of the small vessels, and help us understand how venous problems lead to skin damage.

**Why have you been chosen?**

We are looking for at least 3 patients who are scheduled to have a lower limb amputation.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign and date a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What this study will involve:**

Patients who wish to participate will undergo lower limb amputation at Dunedin Public Hospital. If you are neuropathic (can not feel pain in your limb) and a vascular surgeon has determined that imaging will not cause undue stress or pain, we will ask to image prior to amputation. This should take no more than 30 minutes. During imaging, the limb will be filled via cannula with a dye that allows us to see the blood vessels with a near-infra red, specialized camera. After amputation, your limb will again be imaged with the near-infra red camera. After imaging, the limb will be rinsed with saline, and injected with a resin that will harden into a 3-D map of the blood vessels. The limb will be dissolved, and we will be able to look at the map and compare it to what we imaged with the dye and camera.

**Outcome measures:**

Images of the dye in the blood vessels

Amount of resin able to travel through the blood vessels.

**What are the risks to you?**

The investigation of the lower limb, once amputated, will carry no extra risk to you as a participant. Amputation involves standard risks, including anaesthetic risk and risk of infection. These risks will be managed by your surgical team as part of your care.

**What if something goes wrong?**

Every effort will be made to ensure your safety and well being during this study. If you are harmed during this study, you will be compensated by the Accident Compensation Corporation (ACC). If you have any complaints regarding the hospital staff or study investigators, you may contact patient affairs at Dunedin Hospital:

****Ph:**** 03 470 9531 - Enquiries Desk

****Ph:**** 03 470 9534 - Patient Affairs Office

****email:****patient.affairs@southerndhb.govt.nz

****email:**** For Complaint / Compliment feedback-SDHB@southerndhb.govt.nz

**What are the possible benefits?**

The information gained in this study will help us find minimally invasive ways to look at people’s blood vessels, which will help health care providers make more accurate and timely diagnoses.

**Your privacy**

 All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

**What will happen to the study results?**

The results of this study will be analysed by the University of Otago, and published as a paper in a peer reviewed journal. We will also publish a summary of the results and send this summary to all participants.

**Contacts**

Should you have any questions or concerns, please contact one of the study investigators:

Jo Krysa, jo.krysa@southerndhb.govt.nz

Kari Clifford: kari.clifford@gmail.com, 0210668369

**Consent Form**

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**If you need an INTERPRETER, please tell us.**

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

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing my information, including information about my health. | Yes 🞏 | No 🞏 |
| 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 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic 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. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| 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.

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| 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.

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| Researcher’s name: |
| Signature: | Date: |