Participant Information Sheet

Trial title:	Aspirin4VLU: A randomised trial of low dose aspirin for venous leg ulcers
Ethics committee ref:	
Local Investigator	[Specific site details inserted]
Lead investigator:	Associate Professor Andrew Jull National Institute for Health Innovation, University of Auckland 09 923 4259
Project Manager:	Angela Wadham National Institute for Health Innovation, University of Auckland 09 923 2337

You are invited to take part in a trial of aspirin for treating venous leg ulcers.

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 won't affect the care you receive.

This Participant Information Sheet will help you decide if you would like to take part. It tells you why we are doing the trial, what it would involve for you, what the benefits and risks might be, and what would happen after the trial ends. The research nurse will go through this information with you to answer any questions. You do not have to decide today whether or not you will participate in this trial. Before you decide you may want to talk about the trial with other people, such as family, whanau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this trial, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of this document to keep.

What is the purpose of the trial?

This clinical trial is funded by the Health Research Council of New Zealand. It is co-ordinated by researchers at the University of Auckland. The aim is to find out whether using low-dose aspirin capsules (150mg - half the strength of usual aspirin) as well as compression bandaging speeds up venous leg ulcer healing. Some studies suggest aspirin might help venous ulcer healing, but they have been too small to provide an answer.

In this trial half of the participants will get low-dose aspirin capsules to take every day and the other half will get placebo capsules to take every day. A placebo capsule looks like the aspirin capsule but contains no aspirin. Who gets which capsule will be random (50:50 chance) and nobody will know until after the trial which capsule they were taking. Creating

groups this way will mean the two groups are alike except for taking aspirin or not. Comparing ulcer healing in the two groups will then show whether there is any difference in ulcer healing caused by taking aspirin.

What will my participation in the trial involve?

We are inviting 354 people with venous leg ulcers to take part in the clinical trial. You have been invited because you have a venous leg ulcer. If you decide to take part, a research nurse will visit you three times. The visits will be where you would normally receive a district nurse visit (i.e. your home or a clinic). Each visit will take about 30-60 minutes. The research nurse is a qualified district nurse with experience in leg ulcer care.

At the first visit the research nurse will explain the trial and check that you can enter the trial. The research nurse will also look after your leg ulcer at this visit instead of the district nurse. You will be asked if you want to take part in this trial and asked to sign a consent form if you do.

If you sign the consent the research nurse will ask you some questions about your medical history, about your leg ulcer and may need to measure your blood pressure at your arm and at your ankle. Consent also includes permission to contact your GP to ensure you are able to take aspirin. If your GP tells the research nurse you are not able to take aspirin (or that you should be taking aspirin), the research nurse will phone you with this information and you cannot take part in the trial.

If you still meet all the entry criteria the research nurse will arrange another visit (visit 2). They will ask you some more questions, measure your ulcer and ask you to complete a questionnaire about your health. The research nurse will look after your leg ulcer at this visit and give you the trial capsules.

At the third visit (6 months after the second visit) the research nurse will visit again to check whether your ulcer has healed. If your leg ulcer has healed, the research nurse will need to look at your district nursing records to see what date your leg ulcer healed. The research nurse will ask you to complete a questionnaire about your health. You will also be asked to complete a survey about participating in the trial. The research nurse will look after your leg ulcer at this visit.

In between the second and third trial visits, your usual district nurse will continue to look after your leg ulcer and check if it has healed. If your ulcer heals between the second and third research nurse visits, you will need to stop taking the trial capsules. If you want to contact the research nurse in between these visits, you can do so.

What are the possible benefits and risks of this trial?

Possible benefits

Your participation in this clinical trial will improve our understanding of the effect of low dose aspirin (150 mg) on venous leg ulcers and may improve the treatment of leg ulcers for others in the future.

Possible risks

Aspirin is a drug that has side effects. The common side effect is upset stomach. Uncommon side effects include any gastric bleeding, bleeding that requires going to hospital for transfusion (major bleeding), and stroke caused by bleeding.

In people without diseases that need to be treated with aspirin, the rate of major bleeding that requires transfusion or causes death is 10 per 10,000 people per year when taking aspirin and 7 per 10,000 people per year when not taking aspirin. The rate of stroke caused

by bleeding is 4 per 10,000 people per year when taking aspirin and 3 per 10,000 per year when not taking aspirin.

The risk of bleeding increases with age or if you have diabetes or if you smoke tobacco. The risk of bleeding is not affected by the type of aspirin or the dose of aspirin.

You will be issued a card to confirm your participation in a clinical trial. Please show this card to health professionals at the time of any treatment (including going to the dentist or chemist).

You may need to stop taking the trial capsules:

- If you are admitted to hospital.
- If you start having side effects of aspirin.
- If you start taking new medications that should not be taken with aspirin.
- If your GP or other doctor thinks you should stop taking aspirin.
- If your GP or other doctor thinks you should definitely start taking aspirin.

Nobody knows whether you will be on the aspirin or placebo capsules. If you need to stop taking aspirin, or you need to start taking aspirin, you will need to stop taking the trial capsules.

Who pays for the trial?

Taking part in this clinical trial will not cost you any more than you pay now for receiving care from district nurses for your leg ulcer.

What if something goes wrong?

If you were injured in this trial, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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 trial won't affect your cover.

What are my rights?

You do not have to take part in this trial. If you do not take part, your care will not be affected. If you agree to take part in the trial, you can stop taking the trial capsules at any time, or withdraw from the trial at any time. If you stop taking the trial capsules, we would still like to contact you at 6 months to see if your leg ulcer has healed. If you withdraw from the trial we would like to use your information up to the point you withdraw.

The trial files and all information that you provide will be strictly confidential. No material that could identify you will be used in any reports on this trial. The information will be kept at the National Institute for Health Innovation, the University of Auckland. All computer records will be password protected and paper records stored in a secure storage facility. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994.

During the trial only the Aspirin4VLU researchers and the trial monitor will have direct access to your information. Representatives of Medsafe or the ethics committee may also require access. This access will only be to check the accuracy of the information collected for the trial and the information will remain confidential.

As a participant you have the right to access your information and to correct your information in the trial documents. Ask the research nurse how to do this. You also have the right to

services of an appropriate standard. This means that if we learn of any new information about aspirin that will have a positive or negative effect on your health, we will inform you as soon as possible.

What happens after the trial?

You will remain on the trial capsules for 6 months at the most. If your leg ulcer heals before 6 months are completed you will need to stop taking the trial capsules then. At the 6 month visit, the research nurse will ask for any remaining trial capsules to be returned. If your leg ulcer is still not healed, we recommend you do not take aspirin until the trial results are known. You should discuss with your GP whether taking aspirin for other reasons is needed.

When all participants have completed the trial, the data will be analysed and published. At the earliest, this will be about 2 ½ years after the first person started on the trial. We will then notify you of the results by email or post. We will tell you which capsule you were on (aspirin or placebo). We may be asked to submit individual participant data to a clinical trials register in order to have the results published in a well-known journal. If we are required to submit data to such a register, you would not be able to be identified.

We will keep your information for 10 years after the trial is completed.

Your data may be used in a study called a meta-analysis. This type of trial collects individual participant information from all trials of aspirin for venous leg ulcers. If we do share your data for such a study, you would not be able to be identified.

Who do I contact for more information or if I have concerns?

If you want to talk to someone who isn't working on the trial, you can contact a health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Maori health support please contact :

[Insert locality details - Name, position
Telephone number
Email]

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this trial on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

This clinical trial is registered on the website *ClinicalTrials.gov* [NCT02158806].

Consent Form

Aspirin4VLU: A randomised trial of low dose aspirin for venous leg ulcers

Please tick to indicate your agreement to the following

I have read, and I understand the Participant Information Sheet.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not to participate in this trial.	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 trial.	Yes ☐	No ☐
I am satisfied with the answers I have been given regarding the trial.	Yes ☐	No ☐
I understand that taking part in this trial is voluntary (my choice) and that I may withdraw from the trial at any time without this affecting my clinical care.	Yes ☐	No ☐
If I decide to withdraw from using the trial tablets, I agree to be contacted at 6 months for a follow-up visit.	Yes ☐	No ☐
If I decide to withdraw from the trial, I agree that the information collected about me up to the point when I withdraw may continue to be used.	Yes ☐	No ☐
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐	No ☐
I consent to my GP or current provider being contacted about my participation in the trial and being asked about my qualifying to be part of the trial.	Yes ☐	No ☐
I understand that there may be risks associated with the treatment.	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 clinical records for the sole purpose of checking the accuracy of the information recorded for the trial.	Yes ☐	No ☐
I understand that my participation in this trial is confidential and that no material, which could identify me personally, will be used in any reports on this trial.	Yes ☐	No ☐
I understand the compensation provisions in case of injury during the trial.	Yes ☐	No ☐
I know who to contact if I have any questions about the trial in general.	Yes ☐	No ☐
I understand my responsibilities as a trial participant.	Yes ☐	No ☐
I understand that information may be shared with other studies or registers but that no information that identifies me personally will be used.	Yes ☐	No ☐
I wish to receive a summary of the results from the trial.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this trial.

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 trial and has given informed consent to participate.

I will ensure a copy of the Participant Information Sheet and Informed Consent Form is provided to the participant.

Researcher's name: _____

Role in Project: _____

Researcher's contact phone number: _____

Signature: _____ Date: _____