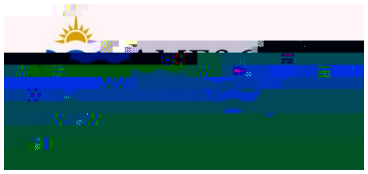

# METforMIN for Treating Peripheral Artery Disease-Related Walking Impair4o7ai

This study aims to recruit 116 people with PAD across a number of sites in Queensland. Approximately half of these participants will be randomly allocated to take metformin and the other half to take a placebo. All participants will be asked to take up to one 500mg capsules three times per day with food.

**This study will measure the change in walking distance after 6 months of taking the drug.** Walking distance will be measured using a 6 minute walk test assessment. The study will also measure the change in:

- Physical activity levels over 7 days using an activity monitor
- Markers in the blood related to peripheral artery disease
- Health related quality of life, and
- Lower limb blood supply

This study has been initiated by Professor Jonathan Golledge at the Queensland Research Centre for Peripheral Vascular Disease, James Cook University and the Townsville Hospital, Townsville. This research is being conducted at multiple sites and include The Townsville Hospital, QLD; Princess Alexandra Hospital, Woolloongabba, James Cook University, Townsville, QLD; The Royal Brisbane and Women's Hospital, Herston, QLD and The Prince Charles Hospital, Chermside West, QLD.

## What does participation in this research involve?

**Visits to the Study Centre:**

If you decide to take part in this research trial you will be asked to make a minimum of four (4) visits to the study centre **The Townsville Hospital.**

| Week | Type of Involvement | Details of Involvement | How much Study Drug to take |
|---|---|---|---|
| **1** | **Phone call 1** | | |

You will receive weekly phone calls from the study coordinator to ask you:

If you have taken the study drug as instructed and if the dose has been tolerated.
If you had been experiencing any side effects to the medication such as gastrointestinal upset
If you had experienced any changes to your health

Based on your answers, the coordinator will instruct you if you need to change the

## What do I have to do?

By agreeing to take part in this study, **you agree to take part in all the research activities in this booklet and take the study drug as directed unless told to stop by the coordinator or senior member of the research team**.

Your participation in this study will not prevent or restrict you from taking your normal medication, participating in any normal activities of daily living or attending other appointments.

While taking part in this study **it is advisable that you do not participate in any other drug studies** due to the potential impact it may have in this study.

## Other relevant information about the research study

There are no additional costs associated with participating in this research study, nor will you be paid. All medication, tests and medical care required as part of the research study will be provided to you free of charge.

You will be reimbursed for your time and travel costs associated with the research study visit. Travel costs will be limited to parking or community flyer transport and reimbursement for your time will be to the amount of $100. This will be provided in the form of gift vouchers that will be given in three instalments, $25 after successfully attending screening visit, $25 after successful randomization and $50 upon the completion of the study.

## Do I have to take part in this study?

**Participation in any research project 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 project at any stage.

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

Before you make your decision, you can speak to a member of the research team so that you can ask any questions you have about the research project. Sign the consent form only after you have had a chance to ask your questions and have received satisfactory answers.

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 **The Townsville Hospital.**

If you decide to withdraw from this trial, please notify a member of the research team before you withdraw and you will be sent a study withdrawal form to complete. The data collected from you up to the date of withdrawal will be stored and used according to the research protocol unless you ask for your samples and data be destroyed.

## What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at **The Townsville Hospital.** If you decided not to participate, you will continue to visit your GP and/or vascular surgeon as you would normally. Please note, **participation in this study does not replace your usual care** received from your GP and/or vascular surgeon. You are encouraged to continue seeing your doctors as normal while participating in this study.

Once the study has concluded, with your consent, any remaining blood sample will be kept and potentially used for other related research purposes. The consent for keeping these samples will be given on a separate consent form and is not included in the consent for this MERIT study. This consent is not a condition for participating in this study.

## What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment. If this happens, your study doctor will advise you and discuss whether you want to continue your participation. If you decide to withdraw, your study doctor will make arrangements for

results, however

# **Consent Form -** Adult providing own consent

| | |
|---|---|
| **Title** | **MEtfoRmIn for Treating Peripheral Artery Disease-Related Walking Impairment** |
| **Short Title** | MERIT |
| **Protocol Number** | 2.3 |
| **Chief Principal Investigator** | Professor Jonathan Golledge |
| **Site Principal Investigator** | Professor Jonathan Golledge |
| **Site Coordinator** | Mrs Lisan Mulvey |
| **Location** | The Townsville Hospital |