

## ASPiVLU Study: ASPIrin in Venous Leg Ulcer healing

### Background

Venous leg ulcers (VLUs) are a common and costly problem worldwide. In 2010 an estimated 400,000 Australians were treated for VLU's. VLUs are a chronic wound problem managed in general practice and community settings. People with chronic venous insufficiency (CVI) are prone to developing VLUs on ankles and lower legs. These wounds occur spontaneously or after minor trauma. Ulcers are often painful and heavily exudating and due to underlying disease mechanisms, healing is protracted and ulcer recurrence common. The natural history of a VLU is a cycle of healing and recurrence which has a considerable impact on individual's health, quality of life and socioeconomic costs. The burden of venous ulceration is expected to rise with an ageing population and the growing epidemics of diabetes and obesity – all risk factors for the development of VLUs.

### What is the purpose of this study?

The main treatment for VLUs is a firm compression bandage to aid venous return. It assists by reducing venous hypertension, enhancing blood flow and reducing peripheral oedema (swelling). Although compression is used to treat VLUs, studies show that it only has moderate effects on healing with up to 30 to 50% of VLUs remaining unhealed after two years of compression. Furthermore, up to one in three affected individuals with VLUs experience more than ten episodes of ulceration in a lifetime with recurrence rates estimated between 30 and 80% and many ulcers recurring within three months of healing; possibly due to a prolonged inflammatory response.

Aspirin is a widely used drug that has several actions potentially capable of influencing the progression of VLUs. Animal studies suggest that aspirin 300mg will suppress inflammation and promote ulcer healing. Data from two clinical studies from the UK and Spain suggest that aspirin (as an adjunct to compression) may speed healing rates and possibly prevent VLU recurrence, however robust evidence for effectiveness of aspirin from high quality randomised controlled trials is lacking.

The aim of the study is to therefore assess whether daily treatment with 300mg aspirin in addition to compression can improve time to healing and reduce incidence of ulcer recurrence. This finding may improve the quality of life and reduce treatment costs for a large number of people in the future. If proved effective the low cost of aspirin therapy would make it an affordable therapeutic agent for people with VLUs worldwide.

This research is being conducted by Monash University and has been funded by the National Health and Medical Research Council. It has been approved by the Alfred Hospital Human Research Ethics Committee (Project No. HREC/14/Alfred/2).

## The Investigators

### Principal Investigator:

Dr Carolina Weller

Address: Department of Epidemiology and Preventative Medicine, Monash University  
Level 6 Alfred Centre, Commercial Road, Melbourne, VIC 3004, Australia

Tel: 03 9903 0623

Email: [med-aspiylu@monash.edu](mailto:med-aspiylu@monash.edu)

### Project Manager (general enquiries):

Dr Rosemary McGinnes

ASPiVLU Study Coordinator

Department of Epidemiology and Preventive Medicine, Monash University

Tel: +61 3 9903 0926

Email: [med-ASPiVLU@monash.edu](mailto:med-ASPiVLU@monash.edu)

### Site Investigators:

- Dr Pat Aldons [Principal Investigator for the Prince Charles Hospital, Queensland]
- Dr Elizabeth Dapiran [Principal Investigator for the Alfred Health and Western Health, Victoria]
- Professor Sinha Sankar [Principal Investigator for Royal Hobart Hospital, Tasmania]
- Dr Mauro Vicaretti [Principal Investigator for Westmead Hospital, NSW]
- Associate Professor Michael Woodward [Principal Investigator for Austin Health, VIC]

This study has been registered with the Australian New Zealand Clinical Trial Registry: [ACTRN12614000293662](https://www.anzctr.org.au/Trial/Registration/Trial.jsp?ACTRN12614000293662)