

# Honey as Adjuvant Leg ulcer Therapy: A randomised controlled trial of a honey-impregnated dressing for venous leg ulcers

<b>Submission date</b> 08/02/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/03/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Andrew Jull

**Contact details**  
Clinical Trials Research Unit  
University of Auckland  
Private Bag 92019  
Auckland  
New Zealand  
1003  
+64 9 373-7599 extn 84744  
a.jull@ctr.u.auckland.ac.nz

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

**Acronym**

HALT

**Study objectives**

The HALT trial is an open-label, multi-centre, randomised, controlled clinical trial assessing the effect of manuka honey on ulcer healing, in patients with venous ulcers. Patients will be randomised to receive either manuka honey dressings or usual care (dressing of clinician's choice) for 12 weeks or until the ulcer has healed, whichever is sooner.

This intervention will be against a background of standard compression therapy. Allocation is by central telephone randomisation. The sample is stratified by ulcer size, ulceration duration and study centre. The objective of the study is to determine the effectiveness of manuka honey as an adjuvant to compression therapy in community-based patients with venous leg ulcers. Where the participant has more than one leg ulcer, the largest ulcer is selected as the reference ulcer.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Auckland Ethics Committee (Committee X). Date of approval: 09/12/2003 (ref: AKX/03/09 /232)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Venous or mixed venous/arterial leg ulcers

**Interventions**

Honey-impregnated calcium alginate dressing as an adjuvant to compression bandaging versus usual care (compression bandaging plus dressing of clinician's choice).

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Manuka honey

**Primary outcome(s)**

Number of participants with completely healed reference ulcers at 12 weeks

**Key secondary outcome(s)**

Time to healing, percentage change in ulcer size, recurrence at six months, health related quality of life, number of dressing changes, costs, and adverse events.

**Completion date**

31/08/2005

## **Eligibility**

**Key inclusion criteria**

400 community-based participants treated by district nurses, each with venous leg ulcer (clinical history, ABI >0.8) or mixed venous/arterial ulcer (clinical history, ABI >0.7), and being treated with compression bandaging.

ABI = Ankle Brachial Index

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Unable to provide informed consent
2. Have pre-existing diagnosis of diabetes
3. Have pre-existing diagnosis of rheumatoid arthritis
4. Have allergy to honey

**Date of first enrolment**

01/05/2004

**Date of final enrolment**

31/08/2005

## **Locations**

**Countries of recruitment**

New Zealand

**Study participating centre**

Clinical Trials Research Unit  
Auckland  
New Zealand  
1003

## Sponsor information

### Organisation

Health Research Council of New Zealand

### ROR

<https://ror.org/00zbf3d93>

## Funder(s)

### Funder type

Research council

### Funder Name

Primary funder: Health Research Council of New Zealand, grant No: 03/087.

### Funder Name

Additional support: ApiMed Medical Honey Ltd and USL Medical Ltd

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/02/2008		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes