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

Submission date 08/02/2004	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered [_] Protocol
<b>Registration date</b> 22/03/2004	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 13/02/2008	<b>Condition category</b> Circulatory System	[] Individual participant dat

#### Plain English summary of protocol

Not provided at time of registration

Study website http://www.ctru.auckland.ac.nz/research/halt/index.html

# **Contact information**

Type(s) Scientific

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

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#### ClinicalTrials.gov number

Secondary identifying numbers 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

**Secondary study design** Multi-centre

**Study setting(s)** Not specified

**Study type(s)** Treatment

#### Participant information sheet

#### 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 honev

#### Primary outcome measure

Number of participants with completely healed reference ulcers at 12 weeks

#### Secondary outcome measures

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.

#### Overall study start date

01/05/2004

#### **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

**Age group** Adult

**Sex** Both

**Target number of participants** 400

Key exclusion criteria

1. Unable to provide informed consent

2. Have pre-exisiting 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

#### Sponsor details

PO Box 5541 Wellesley St Auckland New Zealand 1001 +64 9 379 8227 bscoggins@hrc.govt.nz

#### Sponsor type

Research council

#### 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**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	Results	01/02/2008		Yes	No