

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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? |
|---------------------------------|---------------|--------------|------------|----------------|-----------------|
| Results article | Results | 01/02/2008 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |