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

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

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

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 honey

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
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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