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Randomised controlled trial (RCT) and economic modelling to evaluate the place of anti-microbial agents in the management of venous leg ulcers

Submission date 17/02/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/02/2004	**Overall study status** Completed	
Last Edited 08/12/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 02/10/02

Study information

Scientific Title

Acronym
VULCAN

Study objectives
Are anti-microbial treatments for venous leg ulcers cost-effective?

Please note that, as of 16/01/2008, the start and anticipated end date of this trial have been updated from 01/04/2004 and 31/03/2007 to 01/07/2004 and 31/07/2008, respectively.

Please note that, as of 27/08/2009, the anticipated end date of this trial has been updated from 31/07/2008 to 31/01/2010.

Please note that the target number of participants was added as of 07/09/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Sheffield LREC, approved in April 2004 (ref: NS2003 11 1799)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Venous ulcers

Interventions
RCT group:
One group will have a standard non-adherent dressing applied beneath compression bandages. The other will have an anti-microbial dressing applied beneath compression bandages.

Added as of 08/09/2009:
Those patients (n= 91) who were not eligible or did not wish to take part in the RCT were invited to participate in the observational arm of the study. In this arm the treatment was entirely at the discretion of the responsible clinician and the patient. However, information about the dressing, outcomes and subsequent clinical assessments followed the protocol for the randomised trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 08/09/2009:
1. Number of ulcers completely healed at 12 weeks
2. Cost data from the RCT and observation arms at 12 weeks

Information provided at time of registration:
1. Cost data will be collected from the observational database and RCT
2. Clinical end point for the RCT group: time to complete healing of the leg ulcer

Key secondary outcome(s))
Current information as of 08/09/2009:
1. Recurrence rate at six months and one year
2. Quality of life (SF-36® Health Survey, Euroqol EQ-5D and Standard Gamble [SG]) at 1, 3, 6 and 12 months
3. Symptomatic data (including pain) collected weekly until 12 weeks or ulcer healed

Information provided at time of registration:
1. Recurrence rate
2. Quality of life (SF-36® Health Survey, Euroqol EQ-5D and Standard Gamble [SG])
3. Symptomatic measures, including pain

Completion date
31/01/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/09/2009:
Patients with an unhealed venous leg ulcer that had been present for longer than 6 weeks.

Inclusion criteria provided at time of registration:
Patients with an unhealed venous leg ulcer.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Added as of 07/09/2009:
1. Refusal to give informed consent to participating in the RCT
2. Insulin controlled diabetes mellitus
3. Pregnancy

4. Sensitivity or specific contra-indications to the use of silver
5. Ankle/brachial pressure index of less than 0.8 in the affected leg
6. Leg ulcers with a maximum diameter of less than one centimetre
7. Atypical ulcers, including those where there was suspicion of malignancy, co-existing skin conditions, or vasculitis
8. Patients on oral or parenteral antibiotic treatment

Date of first enrolment
01/07/2004

Date of final enrolment
31/01/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Vascular Institute
Sheffield
United Kingdom
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Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	01/11/2009		Yes	No
Protocol article	protocol	01/04/2007		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes