

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

<b>Submission date</b> 17/02/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/12/2009	<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

Prof Jonathan Michaels

### Contact details

Sheffield Vascular Institute  
Northern General Hospital  
Sheffield  
United Kingdom  
S5 7AU  
+44 (0)114 226 9124  
[jonathan.michaels@sth.nhs.uk](mailto:jonathan.michaels@sth.nhs.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

For RCT: <http://www.shef.ac.uk/content/1/c6/06/48/22/Info%20sheet.pdf>. For observation group: <http://www.shef.ac.uk/content/1/c6/06/48/22/obsMay05.pdf>

## 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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/07/2004

## **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

300

**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**

England

United Kingdom

**Study participating centre**

Sheffield Vascular Institute

Sheffield

United Kingdom

S5 7AU

# Sponsor information

## Organisation

Department of Health (UK)

## Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

Sheila.Greener@doh.gsi.gov.uk

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/en/index.htm>

## ROR

<https://ror.org/03sbpja79>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

# 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?
<a href="#">Protocol article</a>	protocol	01/04/2007		Yes	No
<a href="#">Results article</a>	results	01/11/2009		Yes	No