

# Treatment with doxycycline to promote the healing of chronic venous ulcer and markers of chronic venous insufficiency

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/02/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Kevin Burnand

### Contact details

Guy's and St Thomas' NHS Foundation Trust  
General, Vascular and Colorectal Surgery Department  
F01 North Wing  
St Thomas' Hospital  
Lambeth Palace Road  
London  
United Kingdom  
SE1 7EH  
+44 (0)20 7188 2570  
Kevin.burnand@kcl.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0013146069

# Study information

## Scientific Title

Treatment with doxycycline to promote the healing of chronic venous ulcer and markers of chronic venous insufficiency: a randomised controlled trial

## Study objectives

1. Is haemosiderin a reliable marker for venous insufficiency?
2. Does the inhibition of matrix metalloproteinase play any role in the healing of ulcer?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## 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

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Cardiovascular: Venous ulcers

## Interventions

Patients will be randomised into either treatment or control group. Each group will be matched according to ulcer size. The treatment group will take two daily 100mg of doxycycline and the patients in the control group will take matched placebo tablets. A biopsy from the ulcer will be obtained before the start of the study and at 8 weeks. Sample will be used to determine the Matrix Metalloproteinase (MMPs) level.

## Intervention Type

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Haemosiderin

**Primary outcome measure**

Ulcer sizes, complete or incomplete healing

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/09/2003

**Completion date**

01/12/2007

## **Eligibility**

**Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

60 patients will be recruited from the venous ulcer out patients clinic at St Thomas' Hospital

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

01/12/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Guy's and St Thomas' NHS Foundation Trust**

London

United Kingdom

SE1 7EH

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Guy's and St. Thomas' NHS Foundation Trust (UK)

**Funder Name**

Own Account - NHS R&D Support Funding

# 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