

Randomised controlled trial of the effectiveness of low level laser therapy given by District Nurses in the treatment of chronic wounds and ulcers on the lower leg

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/04/2014	Condition category 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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0670159738

Study information

Scientific Title

Study objectives

Laser therapy in chronic wound management

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Leg ulcer

Interventions

Comparison of conventional treatment (bandages and ointments) versus conventional treatment + twice weekly low level laser treatment for 12 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Patients self-assessment of pain and interference with life, change in size or healing of wound or ulcer, number of days on antibiotic treatment

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2004

Completion date

28/02/2006

Eligibility

Key inclusion criteria

1. Age > 18
2. Lower leg wound or ulcer for > 6 weeks not responding to conventional treatment.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Sample size 135. Stratified randomisation for patients with diabetes or rheumatoid arthritis.

Key exclusion criteria

1. Pregnant
2. Known or suspected lower leg malignancy
3. Photosensitivity
4. Transplant patient
5. Laser treatment to affected leg in last 6 months

Date of first enrolment

01/02/2004

Date of final enrolment

28/02/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Swithun's House
Bridport
United Kingdom
DT6 5DX

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

Wessex Primary Care Research Network RM&G Unit, South West Dorset PCT (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