

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

Protocol serial number

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

St Swithun's House

Bridport

United Kingdom

DT6 5DX

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration