ISRCTN80835416 https://doi.org/10.1186/ISRCTN80835416

A comparative study of the therapeutic effects of continuous and pulsed laser light on wound healing rates.

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2011	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter Vowden

Contact details
Department of Vascular Surgery
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
+44 (0)1274 364466
peter.vowden@bradfordhospitals.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0050058361

Study information

Scientific Title

Study objectives
The study will investigate whether the effect of pulsed infra-red (IR) laser illumination of wounds can be distinguished from placebo therapy and continuous laser IR illumination and if the responses to pulsed laser therapy correlate with the responses to frequencies used in an earlier study of pulsed electromagnetic fields.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-blinded 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
Injury, Occupational Diseases, Poisoning: Wound healing

Interventions
80 minimum in four groups each of 20 subjects:
A will be the control group, receiving no IR therapy.
B will receive IR laser therapy pulsed at 292 Hz.
C will receive IR laser therapy pulsed at 700 Hz.
D will receive continuous IR laser illumination.

Each subject will be assessed on recruitment to the study and given a treatment session twice per week for four weeks. This will be followed by a 4-week observation period ending with the

final assessment. After the initial assessment, subjects will be assessed at the ends of weeks 1 - 4 and 8 with a follow-up observation at the end of week 13. Patients' subjective comments will be sought throughout.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The study will test the 'null hypotheses' that there are no significant differences between the control group and any other group at the 95% confidence level.

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/07/1999

Completion date
31/07/2003

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
80 minimum in four groups each of 20 subjects

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
06/07/1999

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Vascular Surgery
Bradford
United Kingdom
BD9 6RJ

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
Bradford Teaching Hospitals NHS Foundation Trust (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?
Abstract results		01/09/2003		No	No