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
30/09/2005	No longer recruiting
Registration date	**Overall study status**
30/09/2005	Completed
Last Edited	**Condition category**
25/08/2011	Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

Protocol serial number
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

Primary study design
Interventional

Study design
Double-blinded randomised controlled trial

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/07/2003

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Bradford Teaching Hospitals NHS Foundation Trust (UK)

Results and Publications

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