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# 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

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## 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
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**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 |