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

| Submission date                  | <b>Recruitment status</b> No longer recruiting              | Prospectively registered       |  |  |
|----------------------------------|-------------------------------------------------------------|--------------------------------|--|--|
| 30/09/2005                       |                                                             | ☐ Protocol                     |  |  |
| Registration date                | Overall study status                                        | Statistical analysis plan      |  |  |
| 30/09/2005                       | Completed                                                   | [X] Results                    |  |  |
| <b>Last Edited</b><br>25/08/2011 | Condition category Injury, Occupational Diseases, Poisoning | [] 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

#### Study design

Double-blinded randomised controlled trial

#### Primary study design

Interventional

#### 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              |