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1450nm Smoothbeam diode laser in inflammatory acne vulgaris - a split-face randomised controlled trial.

Submission date	Recruitment status
28/09/2007	No longer recruiting
Registration date	**Overall study status**
28/09/2007	Completed
Last Edited	**Condition category**
18/04/2012	Skin and Connective Tissue Diseases

[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0227186079

Study information

Scientific Title

Study objectives
Does the 1450nm diode laser improve inflammatory acne vulgaris? To determine whether the 1450-nm diode laser is effective treatment for facial inflammatory acne vulgaris using a split-face randomized controlled trial (one half of the face is treated with the other acting as a control).
1. Primary objective: To determine whether a course of 3 treatments with the 1450-nm diode laser produces a significant difference in acne lesion counts (both inflammatory and non-inflammatory lesions), between the treated and control sides of the face, assessed every 4 weeks after the first treatment by a blinded assessor. 2. Secondary end-points:
2.1 To determine whether the 1450-nm diode laser treatment produces a significant difference in acne as judged using clinical photographs to compare the right and left sides of the face, assessed every 4 weeks after the first treatment by a blinded assessor
2.2 To determine the magnitude of any response to the 1450-nm diode laser treatment using lesion counts to compare the right and left sides of the face
2.3 To determine whether response to acne treatment is modified by other factors such as age, sex, severity or duration of acne
2.4 To determine whether the 1450-nm diode laser produces any adverse effects as determined by the treating doctor, who is not blinded to the treatment allocation
2.5 To determine whether any improvement in the inflammatory acne results in an acceptable cosmetic endpoint for the patient using a simple patient questionnaire
2.6 To determine how long it takes to produce any improvement in inflammatory acne and after how many sessions?
2.7 To determine how long any improvement in acne is maintained for
2.8 To determine what percentage of patients do not achieve a cosmetically acceptable endpoint with laser therapy and who therefore need to proceed to treatment with isotretinoin

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Spit-face randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Skin and Connective Tissue Diseases: Acne vulgaris

Interventions
A fixed weekly period or session will be dedicated to recruit and review study participants. Other appointment times will be arranged at the convenience of patients unable to attend the fixed session.

1. Initial assessment
1.1 Consideration for eligibility for inclusion: selection criteria
1.2 Detailed verbal and written information on study purpose, design and patient input with the opportunity to address patient questions. Explanation of the study laser and side effects
1.3 Obtain written informed consent
1.4 Current acne treatment and date of commencement documented
1.5 Patients general practitioner informed of patients entry into the study.

2. First treatment (week 0)
2.1 Address any outstanding issues
2.2 Assessment with lesion counts (Revised Leeds acne grading) of both sides of the face. Clinical photographs taken
2.3 Assign patient study number and give patient sealed envelope stating the side of face to be treated
2.4 Patient takes envelope to person performing treatment in laser clinic
2.5 Patient receives first treatment

3 Assessment and second treatment (week 4)
Assessor:
3.1 Assess acne on both sides of the face with lesion counts (Revised Leeds acne grading)
3.2 Take clinical photographs (before treatment)
Person giving treatment:
3.3 Note any adverse effects from previous treatment
3.4 Treat allocated side of the face
3.5 Patient satisfaction questionnaire

4 Assessment and third treatment (week 8)
As for 3.5, post-treatment assessment every 4 weeks Assessment every 4 weeks with lesion counts (Revised Leeds acne grading) and clinical photographs up until 12 months post treatment or withdrawal from the study. GP informed at completion of the study. Clinical photographs assessed by dermatologists blinded as to which side of the face was treated.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Change in lesion counts (Revised Leeds acne grading) comparing the side of face treated with the untreated side
2. Change in clinical photographs as assessed by consultant dermatologists blinded as to which side of the face was treated.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2005

Completion date
30/10/2007

Eligibility

Key inclusion criteria
Support from Dr. R. Bellamy - Trust advisor on statistics.

Inclusion criteria: patients with mild or moderate acne vulgaris who have not had a cosmetically acceptable response to their current treatment. This treatment may include any topical treatment or systemic antibiotics or hormonal treatment or no treatment.

We aim to recruit patients from the Dermatology outpatient department at The James Cook University Hospital. Identified patients will then be referred to a dedicated clinic led by the principal investigator. At the study clinic the patient will be informed of the study design and objectives. Written information will be provided and any questions addressed. The patient will be invited to participate and written consent obtained. The patient will have as long as he or she requires to decide whether or not to enter the study.

Randomisation will be performed by a statistician who is not involved in the running of the study. A sealed envelope system will be used to ensure that the next treatment allocation is not known, when a patient is being recruited for the study. At no point will the assessors be aware of which side of the face has been treated. The patient and the person performing the treatment will be aware of which side of the face is being treated.

It is felt by the study investigators that if fewer than one third of treated patients obtain any benefit from laser treatment then the treatment will not be of any real clinical value. One third of treated patients obtaining some clinical benefit is equivalent to 67% of patients having the treated side scored as the better side (as 50% would be expected to have fewer lesions on the treated side if the treatment had no benefit at all). To achieve 80% power to show a statistically significant difference (with 95% confidence) in the number of patients for whom the laser-treated side of the face is scored as better than the control side, if the laser treated side is better in at least 67% of patients would require 142 patients. We will recruit 160 patients to allow for 18 subjects not to complete the 12 week assessment and to still have 142 patients in the final analysis.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
160

Key exclusion criteria
1. Less than 16 years of age
2. Female patients who are pregnant or breastfeeding (or who are attempting to become pregnant)
3. Patients in whom systemic treatment with isotretinoin is indicated
4. Patients with a history of hypertrophic or keloid scarring
5. The use of dermal fillers in the previous 3 months
6. Patients with facial hair eg beard or moustache in whom assessment will be difficult

Date of first enrolment
01/10/2005

Date of final enrolment
30/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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SW1A 2NL
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS 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?
Results article	results	01/12/2011		Yes	No