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A preliminary observational study on the effect of pulsed dye laser treatment in patients with facial acne vulgaris.

Submission date
30/09/2005

Recruitment status
Stopped

Registration date
30/09/2005

Overall study status
Stopped

Last Edited
03/10/2013

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
N0436146535

Study information

Scientific Title

Study objectives
Acne patients are increasingly developing clinically significant antibiotic resistant propionbacterium acnes resulting in the reduced effect of antibiotic therapy. Therefore, there is a need to develop non-antibiotic treatment options. A small study has shown benefit from treatment with a short pulse width 0.35 msec low energy pulsed dye laser used as monotherapy. Due to the expense of this type of treatment, it is important to determine the value of pulsed dye laser treatment as adjuvant therapy in patients receiving conventional antibiotic therapy. Most pulsed dye lasers use a longer 1.5 msec pulse width and the effect of this type of laser as adjuvant therapy for acne also needs to be determined. Therefore the aim of this study is to assess the effect of both an N-lite low energy pulsed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Pulsed dye laser treatment vs standard practice

Added 03/10/2013: This trial was stopped in January 2006 due to poor recruitment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Following treatments given at week 0 and week 4:
1. Reduction in inflamed acne lesion counts
2. Reduction in overall acne grade, non-inflamed acne lesion counts, and total acne lesion counts

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/01/2004

Completion date
01/04/2006

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients with mild to moderate facial acne.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
48 in each group

Key exclusion criteria
Patients with acne conglobata, acne fulminans and secondary care, with underlying diseases or other dermatological conditions that require the use of interfering topical therapy, with photosensitive disorders.

Date of first enrolment
27/01/2004

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dermatology Department
Leeds
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LS1 3EX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK) NHS R&D Support Funding

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