

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 03/10/2013	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 propionibacterium 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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Sponsor information

Organisation

Department of Health

Sponsor details

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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

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