

Topical direct laser pan retinal photocoagulation versus retrobulbar indirect laser photocoagulation - which is more comfortable to the patient?

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/04/2016	Condition category Surgery	<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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0203121465

Study information

Scientific Title

Topical direct laser pan retinal photocoagulation versus retrobulbar indirect laser photocoagulation - which is more comfortable to the patient?

Study objectives

Which of the two treatment modalities, topical direct laser pan retinal photocoagulation and retrobulbar indirect pan retinal photocoagulation laser is more comfortable to the patient?

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Surgery of the eye

Interventions

Randomised controlled trial. Patients undergoing laser treatment either after topical or retrobulbar anaesthesia will be given a visual pain analog score chart. They will be asked to score the pain perceived during the course of the treatment. They will also be given a pain analog score chart to score pain felt during the first 48 h following treatment and the need for taking analgesics. They will be provided with a stamped addressed envelope.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Do patients feel comfortable having pan retinal photocoagulation laser treatment after retrobulbar anaesthesia?

Study endpoints: to compare the subjective comfort between topical anaesthesia direct pan retinal photocoagulation laser, and retrobulbar anaesthesia indirect pan retinal photocoagulation laser.

Secondary outcome measures

Not provided at time of registration

Overall study start date

23/12/2002

Completion date

31/03/2005

Eligibility

Key inclusion criteria

Patients will be selected from the waiting list for laser procedure. A letter will be sent out to them giving them information regarding the proposed research, and on the day of the laser they will be asked about their willingness to take part in the research. Case selection will be random. This is a non-therapeutic research. Patients will be over 16 years of age.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

23/12/2002

Date of final enrolment

31/03/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Devon & Exeter Hospital (Wonford)

Exeter, Devon

United Kingdom

EX2 5BW

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Devon and Exeter 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