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

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
15/04/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] 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
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