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A randomised cross-over pilot study of Entonox for pain relief in ophthalmic laser

Submission date 30/09/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 10/12/2009	**Condition category** Signs and Symptoms	[ ] 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
N0207073131

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised cross-over pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
Entomox for pain relief in ophthalmic laser

Added 10/12/09: trial stopped due to lack of funding/sponsorship and participant recruitment issue

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Entonox

Primary outcome measure
Pain score assessment after each treatment

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2000

Completion date
30/06/2004

Reason abandoned (if study stopped)
Lack of funding/sponsorship + Participant recruitment issue

Eligibility

Key inclusion criteria
Patients attending for a course of laser pan-retinal photocoagulation will undergo a standardised treatment, receiving entonox on alternative visits. A pain score will be assessed after each treatment.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 patients

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2000

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Pauls Eye Unit
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Royal Liverpool and Broadgreen University Hospitals 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