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

Submission date 30/09/2004	Recruitment status Stopped	Prospectively registeredProtocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Stopped	Results
Last Edited	Condition category	Individual participant data
10/12/2009	Signs and Symptoms	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Simon Harding

Contact details

St Pauls Eye Unit 2Z Link Royal Liverpool University Hospital Prescot Street Liverpool United Kingdom L7 8XP +44 (0)151 706 3971 l.gee@liv.ac.uk

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 summaryNot provided at time of registration