

A pilot randomised controlled trial comparing the post-operative pain experience following vitrectomy with a 20-gauge system and the new 25-gauge transconjunctival system

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 02/09/2009	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

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

N0141156884

Study information

Scientific Title

Study objectives

To compare post-operative pain following vitreoretinal surgery using 2 different surgical systems.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Obtained in March 2005, ref no 05/Q0602/21

Study design

Single blind 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

Signs and Symptoms: Post operative pain

Interventions

20-gauge system vs new 25-gauge transconjunctival system

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Post-operative pain scores using verbal and visual analogue scales
2. Use of post-operative analgesia

Secondary outcome measures

Post operative pain

Added April 2008:

1. Time taken to perform surgical procedure
2. Post operative inflammation
3. Per-operative and post-operative complications

Overall study start date

01/03/2005

Completion date

01/03/2007

Eligibility

Key inclusion criteria

Added April 2008:

1. Patients with suitable pathology for the 25 gauge system eg macula hole, epiretinal membrane, vitreous opacities
2. Primary vitrectomy

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

50 vitrectomy patients: 25 intervention and 25 controls

Key exclusion criteria

Added April 2008:

1. Previous vitrectomy
2. Unwilling to accept randomisation
3. Unable to give informed consent
4. Pre-operative inflammation

Date of first enrolment

01/03/2005

Date of final enrolment

01/03/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Moorfields Eye Hospital

London

United Kingdom

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Sponsor information

Organisation

Department of Health

Sponsor details

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

Moorfields Eye Hospital NHS Foundation Trust (UK)

Funder Name

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No