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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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
02/09/2009

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
EC1V 2PD

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

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