# 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	Recruitment status No longer recruiting	Prospectively registered		
30/09/2005		☐ Protocol		
Registration date 30/09/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 02/09/2009	Condition category Signs and Symptoms	[] 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

Protocol serial number 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

#### Study type(s)

**Treatment** 

#### 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(s)

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

#### Key secondary outcome(s))

Post operative pain

Added April 2008:

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

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

### 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

**United Kingdom** 

England

### Study participating centre Moorfields Eye Hospital

London United Kingdom EC1V 2PD

## Sponsor information

## Organisation

Department of Health

## Funder(s)

### Funder type

Government

#### **Funder Name**

Moorfields Eye Hospital NHS Foundation Trust (UK)

#### Funder Name

NHS R&D Support Funding

## **Results and Publications**

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