

# A randomised, single-masked, phase IV pilot study of the efficacy and safety of adjunctive intravitreal Avastin® (bevacizumab) in the prevention of early postoperative vitreous haemorrhage following diabetic vitrectomy

<b>Submission date</b> 18/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/06/2016	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

4.1

# Study information

### Scientific Title

A randomised, single-masked, phase IV pilot study of the efficacy and safety of adjunctive intravitreal Avastin® (bevacizumab) in the prevention of early postoperative vitreous haemorrhage following diabetic vitrectomy

### Study objectives

This pilot study is designed to explore and evaluate the feasibility of using pre- and intra-operative intravitreal Avastin® in diabetic vitrectomy for vitreous haemorrhage.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Moorfields and Whittington Research Ethics Committee, 11/07/2007, ref: 07/H0721/58

### Study design

Single-centre randomised single-masked controlled study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Prevention

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

### Health condition(s) or problem(s) studied

Proliferative diabetic retinopathy

### Interventions

Avastin® will be administered intravitreally in a single or dual-dose regimen of 1.25 mg (in 0.05 ml) 2 weeks prior to vitrectomy and at the end of vitrectomy if internal tamponade (oil, air or gas) was not used. No sham intravitreal injections will be given before or after vitrectomy if patient is randomized to the usual treatment group.

### Intervention Type

Drug

**Phase**

Not Applicable

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

Bevacizumab

**Primary outcome measure**

Post-operative vitreous haemorrhage based on two masked clinical assessments at 6 weeks and 6 months.

**Secondary outcome measures**

The following will be assessed at the time of vitrectomy, at 6 weeks and 6 months after vitrectomy:

1. Recruitment and drop out rates
2. Rates of re-operation for recurrent vitreous haemorrhage
3. Rate of post-operative rubeosis and rubeotic glaucoma
4. Rate and severity of intraoperative bleed
5. Mean change in ETDRS acuity and MNRead acuity
6. Serum Avastin® and growth factor levels at 2 and 4-6 weeks after injection. Vitreous levels at 2 weeks after injection.

Safety outcome measures:

1. Incidence and severity of ocular adverse events
2. Incidence and severity of non-ocular adverse events
3. Changes in vital signs

**Overall study start date**

01/10/2007

**Completion date**

30/09/2010

**Eligibility****Key inclusion criteria**

1. A diagnosis of non-clearing or recurrent vitreous haemorrhage due to proliferative diabetic retinopathy - indicated for Pars Plana Vitrectomy (PPV)
2. Visual acuity better than perception of light
3. Patient fit for and agreed to have PPV
4. >20 years old

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Previous vitrectomy
2. Ocular and systemic contra-indication for vitrectomy
3. Unfit for local or general anaesthesia
4. Inability to obtain visual acuity, fundus imaging or fluorescein angiogram
5. Reduced potential visual acuity due to corneal or optic nerve disease, or amblyopia
6. Previous intravitreal Avastin® injection in either eye
7. Inability to give informed consent
8. Inability to comply with follow-up visit and investigation
9. Women of childbearing age
10. Recent (<1 month) acute myocardial infarct, Transient Ischaemic Attack (TIA) or stroke

**Date of first enrolment**

01/10/2007

**Date of final enrolment**

30/09/2010

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Moorfield Eye Hospital**

London

United Kingdom

EC1V 2PD

**Sponsor information****Organisation**

Moorfields Eye Hospital NHS Foundation Trust (UK)

**Sponsor details**

162 City Road

London

England

United Kingdom

EC1V 2PD

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.moorfields.nhs.uk/Home>

**ROR**

<https://ror.org/03zaddr67>

**Funder(s)****Funder type**

Government

**Funder Name**

Moorfields Eye Hospital NHS Foundation 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