

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

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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Moorfield Eye Hospital

London

United Kingdom

EC1V 2PD

Sponsor information

Organisation

Moorfields Eye Hospital NHS Foundation Trust (UK)

ROR

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

Funder(s)

Funder type

Government

Funder Name

Moorfields Eye Hospital NHS Foundation Trust (UK)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes