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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	[ ] Prospectively registered [ ] Protocol
Registration date 11/01/2008	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 14/06/2016	**Condition category** Eye Diseases	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Lyndon da Cruz

Contact details
Moorfield Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD

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

Primary study design
Interventional

Study design
Single-centre randomised single-masked controlled study

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