

Randomised controlled trial of bevacizumab in choroidal neovascularisation secondary to age-related macular degeneration

Submission date 07/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/12/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/08/2013	Condition category Eye Diseases	<input type="checkbox"/> 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
2006-00033-33

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A prospective randomised controlled trial assessing the efficacy of intravitreal bevacizumab in patients with minimally classic and occult choroidal neovascularisation secondary to age-related macular degeneration

Acronym

BeMOC

Study objectives

This study has been designed to compare the difference in central macular thickness at one year between two different treatment regimes. Group 1 has an intravitreal bevacizumab injection at week 0 and is observed 6 weekly with repeat injections as required. Group 2 has an intravitreal bevacizumab injection at week 0, 6 and 12 and is observed 6 weekly with repeat injections as required.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Surrey Research Ethics Committee, the Royal Surrey County Hospital, on 07/11/2006 (ref: 06/Q1909/82)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Age-related macular degeneration

Interventions

Participants will be randomised to the two treatment groups. Group 1 has an intravitreal bevacizumab (Avastin®) injection (1.25mg in 0.05 ml) at week 0 and is observed 6 weekly with repeat injections as required. Group 2 has an intravitreal bevacizumab injection at week 0, 6 and 12 and is observed 6 weekly with repeat injections as required.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bevacizumab (Avastin)

Primary outcome measure

Central macular thickness at baseline, Week 6, 12, 18, 24, 30, 36, 42, 48 and 54

Secondary outcome measures

1. Visual acuity at baseline, Week 6, 12, 18, 24, 30, 36, 42, 48 and 54
2. Fluorescein angiography changes at baseline, Week 24 and 54
3. Quality of life: Visual Function Questionnaire (VFQ-25) at baseline and week 54
4. Adverse events at baseline, Week 6, 12, 18, 24, 30, 36, 42, 48 and 54

Overall study start date

01/11/2006

Completion date

01/11/2008

Eligibility

Key inclusion criteria

1. Age >50 years
2. Fluorescein angiographic evidence of minimally classic or occult choroidal neovascular membrane
3. Best Corrected Visual Acuity (BCVA) 20/40 - 20/320
4. BCVA in no study eye better than 20/320
5. If both eyes are eligible then only the worst eye will be enrolled
6. Willing to attend scheduled visits

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Key exclusion criteria**1. Medical conditions:**

- 1.1. Uncontrolled hypertension
- 1.2. Patients on more than 3 antihypertensive medications
- 1.3. Patients in whom a change in anti-hypertensive drug was initiated within 3 months preceding baseline visit.
- 1.4. Previous thromboembolic phenomenon
- 1.5. On Warfarin or anticoagulants
- 1.6. Recent Myocardial Infarction (MI)
- 1.7. Recent major surgery (within 28 days)

2. Ocular conditions:

3. Glaucoma (IntraOcular Pressure [IOP] >25, on anti-glaucoma treatment, glaucoma surgery)
4. Active intraocular or extraocular inflammation
5. Retinal vascular disease
6. Other sources of choroidal neovascular membrane
7. Previous PhotoDynamic Therapy (PDT)
8. Predominantly classic membranes
9. Previous cataract surgery (within 6 months)
10. Aphakia
11. Other retinal conditions that may effect visual outcome

3. Other:

- 3.1. Allergy to Fluorescein
- 3.2. Inability to obtain colour photographs, fluorescein angiogram, Optical Coherence Tomography (OCT) images
- 3.3. Allergy to anti Vascular Endothelial Growth Factor (VEGF) medications
- 3.4. Allergy to humanised monoclonal antibody
- 3.5. Inability to comply with follow-up procedures

Date of first enrolment

01/11/2006

Date of final enrolment

01/11/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Frimley Park Hospital NHS Trust
Surrey
United Kingdom
GU16 7UJ

Sponsor information

Organisation

Frimley Park Hospital NHS Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00mrq3p58>

Funder(s)

Funder type

Government

Funder Name

Frimley Park Hospital NHS 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013		Yes	No