

Bevacizumab versus ranibizumab in age-related macular degeneration

Submission date 25/04/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/04/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2009	Condition category Eye Diseases	☐ 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
IRB #2034

Study information

Scientific Title
A prospective randomised, double-masked clinical trial comparing bevacizumab to ranibizumab in age-related macular degeneration

Study objectives
Monotherapy with bevacizumab is as effective as monotherapy with ranibizumab for the treatment of exudative age-related macular degeneration (AMD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional review board at the VA Boston Healthcare System gave approval in April 2007.

Primary study design

Interventional

Study design

Prospective double-blinded randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Age-related macular degeneration

Interventions

Intravitreal injection with ranibizumab or bevacizumab based on random allocation.

Dosage: Ranibizumab 0.5 mg/0.05 ml, bevacizumab 1.25 mg/0.05 ml

Method/frequency: Intraocular injections monthly for the first 3 months, following by variable dosing interval on an as needed basis based on clinical judgement

Duration of treatment: one year for study and control group

Duration of follow up: one year in the study with continued follow up as needed in the outpatient clinical setting

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bevacizumab, ranibizumab

Primary outcome(s)

Visual acuity, measured at 6 months and one year

Key secondary outcome(s)

1. Central foveal thickness, measured at 6 months and one year
2. Quality of life assessment, measured at one year

Completion date

07/04/2010

Eligibility**Key inclusion criteria**

1. Exudative AMD involving the foveal centre confirmed by intravenous fluorescein angiography
2. Aged greater than 50 years, either sex
3. Ability to provide informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Previous treatment for exudative AMD in the past one year
2. Presence of subretinal haemorrhage that is greater than 50% of the size of the lesion
3. Advanced glaucoma
4. Any co-existing macular disease causing decreased vision
5. Uncontrolled hypertension
6. History of thromboembolic phenomenon
7. Participation in another concurrent ophthalmic trial

Date of first enrolment

07/04/2007

Date of final enrolment

07/04/2010

Locations**Countries of recruitment**

United States of America

Study participating centre

85 East Concord Street, #8826

Boston

United States of America

02118

Sponsor information**Organisation**

VA Boston Healthcare System (USA)

ROR

<https://ror.org/04v00sg98>

Funder(s)

Funder type

Government

Funder Name

VA Boston Healthcare System (USA) - providing medication costs

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	01/12/2009		Yes	No