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Bevacizumab versus ranibizumab in age-related macular degeneration

Submission date	Recruitment status	[_] Prospectively registered
25/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2009	Eye Diseases	

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.

Study design
Prospective double-blinded randomised controlled trial

Primary study design
Interventional

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