

# Bevacizumab versus ranibizumab in age-related macular degeneration

<b>Submission date</b> 25/04/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2009	<b>Condition category</b> 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

**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?
<a href="#">Results article</a>	results	01/12/2009		Yes	No