

# Choroidal neovascularisation in pathologic myopia: intravitreal ranibizumab versus bevacizumab

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<b>Registration date</b> 01/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/10/2009	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
01/2008

# Study information

## Scientific Title

Choroidal neovascularisation in pathologic myopia: intravitreal ranibizumab versus bevacizumab - a randomised controlled trial

## Acronym

N/A

## Study objectives

Choroidal neovascularisation (CNV) secondary to pathologic myopia (PM) is a known cause of severe visual loss for young and middle-aged patients. Nearly 10% of patients with degenerative retinal findings consistent with high myopia develop choroidal neovascularisation. Although the natural course of myopic CNV is highly variable, the long-term prognosis is known to be poor.

This study compares the efficacy and safety of intravitreal injection of ranibizumab versus bevacizumab in patients with myopic choroidal neovascularisation.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of the Department of Ophthalmology, La Sapienza University of Rome, approved in January 2008

## Study design

Single-centre randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Myopic choroidal neovascularisation

## Interventions

Eligible patients were randomly assigned in a 1:1 ratio to intravitreal injection of ranibizumab (Lucentis®, Genentech, USA) 0.5 mg/0.05 ml or bevacizumab (Avastin®, Genentech, USA) 1.25

mg/0.05 ml in one eye. If both eyes were eligible, the eye with worse visual acuity (VA) was the study eye unless the other eye was deemed more suitable for medical reasons. Both drugs were administered as needed after the first injection.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Ranibizumab (Lucentis®), bevacizumab (Avastin®)

## **Primary outcome measure**

1. Changes in best-corrected visual acuity measured according to a standardised refraction protocol, using the Early Treatment Diabetic Retinopathy Study chart at 4 metres distance by a single, well-trained and experienced orthoptist, who was masked to the study.
2. Changes in foveal centre thickness (microns) measured using the ocular coherence tomography (Stratus® OCT, V4.01, Carl Zeiss Meditec, USA) high-resolution Radial Lines protocol and the Retinal Thickness Map analysis programme.

All primary and secondary outcomes were assessed at study entry and monthly during follow-up (total duration of follow-up: two years).

## **Secondary outcome measures**

The leakage from the CNV was evaluated on fluorescein angiography (ImageNet®, Topcon, Japan), performed by a trained photographer masked to the study, in the late phase (6 - 8 minutes) compared with the early phase (first 1 - 2 minutes). The leakage was compared between the times before and after treatment and was described as absent (CNV closure) or persistent. Recurrence was defined as evidence of leakage from a previously closed CNV.

All primary and secondary outcomes were assessed at study entry and monthly during follow-up (total duration of follow-up: two years).

## **Overall study start date**

01/02/2008

## **Completion date**

31/12/2008

# **Eligibility**

## **Key inclusion criteria**

1. Both males and females, no age limit
2. Pathologic myopia, defined as axial length more than 26.5 mm
3. Subfoveal or juxtafoveal choroidal neovascularisation (CNV), CNV was classified as juxtafoveal if the lesion was closer than 200 microns but not under the geometric centre of the foveal avascular zone
4. Evidence of leakage from CNV on fluorescein angiography

## **Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. Prior treatment for CNV
2. Other ocular diseases that could affect the visual acuity
3. Angioid streaks
4. Trauma
5. Choroiditis
6. Hereditary diseases in the study or the fellow eye
7. Aphakia
8. Previous vitreoretinal surgery
9. Prior history of bleeding diathesis
10. Prior cerebrovascular accident
11. Pulmonary embolus or deep venous thrombosis
12. Myocardial infarction or uncompensated coronary artery disease within the past 6 months
13. Major surgery within the prior 6 weeks
14. Ongoing uncontrolled hypertension

**Date of first enrolment**

01/02/2008

**Date of final enrolment**

31/12/2008

**Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Department of Ophthalmology**

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**Sponsor information**

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**Sponsor type**

University/education

**Website**

<http://www.uniroma1.it/>

**ROR**

<https://ror.org/02be6w209>

**Funder(s)****Funder type**

University/education

**Funder Name**

La Sapienza University of Rome (Italy) - Department of Ophthalmology

**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