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Choroidal neovascularisation in pathologic myopia: intravitreal ranibizumab versus bevacizumab

Submission date	Recruitment status	[ ] Prospectively registered
11/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/10/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/10/2009	Eye Diseases	[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))
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).

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
Rome
Italy
155-00161

Sponsor information

Organisation
La Sapienza University of Rome (Italy)

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
University/education

Funder Name
La Sapienza University of Rome (Italy) - Department of Opthalmology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration