Comparison of bevacizumab (Avastin) and ranibizumab (Lucentis) in exudative age-related macular degeneration.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21233

Source
NTR

Brief title
BRAMD

Health condition

eye; retina; age-related macular degeneration; choroidal neovascularization; angiogenesis; bevacizumab; ranibizumab; oog; retina; leeftijdsgebonden maculadegeneratie; Lucentis; Avastin

Sponsors and support

Primary sponsor: Prof. Dr. R.O. Schlingemann
Department of Ophthalmology, Room A2-122
Academisch Medisch Centrum
Meibergdreef 9
1105 AZ Amsterdam
Tel +31205663616
e-mail: r.schlingemann@amc.uva.nl
Source(s) of monetary or material Support: ZonMw nr. 17088.5606

Intervention

Outcome measures

Primary outcome

The primary outcome is the change in best-corrected visual acuity (BCVA) in the study eye from Baseline to Month 12 assessed with ETDRS-like VA charts at an initial distance of four meter.

Secondary outcome

1. The proportion of patients with a loss of BVCA less than 15 letters from Baseline at 12 months (responders);

2. The proportion of patients with a loss or gain of BVCA less than 15 letters from Baseline at 12 months (stabilizers);

3. The proportion of patients with 15 letters loss or more of BCVA from Baseline at 12 months (losers);

4. The proportion of patients with 15 letters gain or more of BCVA from Baseline at 12 months (gainers);

5. The incidence of fluorescein leakage at 4 and 12 months as well as the change in total area of CNV, total area of leakage from CNV, and total lesion area from baseline at 12 months as determined by the reading centre;

6. Absolute and percent change in retinal thickness, as measured by optical coherence tomography (OCT) at 4 and 12 months as determined by the reading centre;

7. Proportion of dropouts before the final 12 months assessments;

8. Proportion of non-responders at the 4 month assessment;

9. The occurrence of (serious) adverse events during the 12 months of the study;

10. Costs of the two treatments.

Study description

Background summary

The objective of this study is to compare the effectiveness and costs of 1.25 mg of bevacizumab to 0.5 mg ranibizumab, given as monthly intravitreal injections during one year. This will be a randomized, controlled, double masked, clinical trial in 306 patients in five academic trial centres in The Netherlands. The study population consists of patients 60 years of age or higher with primary or recurrent sub- or juxtafoveal CNV secondary to AMD with a total area of CNV of < 12 disc areas and a best corrected visual acuity BCVA score between 78 and 20 letters in the study eye. The primary outcome measure will be the change in best-corrected visual acuity (BCVA) in the study eye from Baseline to Month 12. Secondary outcomes will be amongst others the proportion of patients with a gain of 15 letters or more and/or a BCVA of 20/40 or more at 12 months, and the costs and costs per quality adjusted life-year of the two treatments

Study objective

The primary objective is to demonstrate the non-inferiority of bevacizumab to ranibizumab in the treatment of patients with subfoveal CNV secondary to AMD as determined by the change in best-corrected visual acuity in the study eye from baseline to month 12.

Study design

1. 4 months;

2. 12 months.

Intervention

The included patient is randomized to receive either 1.25 mg bevacizumab or 0.5 mg ranibizumab.
Both investigational treatments will be administered by monthly intravitreal injection for one year (12 injections).

Contacts

Public
R.O. Schlingemann
Department of Ophthalmology, Room A2-122
Academisch Medisch Centrum
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5663616/ +31 (0)20 5663682
Scientific
R.O. Schlingemann
Department of Ophthalmology, Room A2-122

Academisch Medisch Centrum
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5663616/ +31 (0)20 5663682

Eligibility criteria

Inclusion criteria

1. Patients 60 years of age or higher;

2. Patients with primary or recurrent sub-, juxta- or extrafoveal CNV secondary to AMD, including those with RAP, that may benefit from anti-VEGF treatment in the opinion of the investigator;

3. The total area of CNV (including both classic and occult components) encompassed within the lesion must be more or equal to 30% of the total lesion area;

4. The total lesion area should be < 12 disc areas;

5. A best corrected visual acuity (BCVA) score between 78 and 20 letters (approximately 0,63-0,05 Snellen equivalent) in the study eye.

Exclusion criteria

1. Ocular treatment with anti-angiogenic drugs in the last 2 months or Triamcinolone in the last 6 months;

2. Laser photocoagulation (juxtafoveal or extrafoveal) in the study eye within one month preceding Baseline;

3. Patients with angioid streaks or precursors of CNV in either eye due to other causes, such as ocular histoplasmosis, trauma, or pathologic myopia;

4. Spherical equivalent of refractive error in the study eye demonstrating more than ¡V 8 dioptres of myopia;

5. Cataract extraction within three months preceding Baseline;

6. IOP >25 mm Hg;

7. Active intraocular inflammation in the study eye;

8. Vitreous haemorrhage obscuring view of the posterior pole in the study eye;

9. Presence of a retinal pigment epithelial tear involving the macula in the study eye;

10. Subretinal haemorrhage in the study eye if the size of the haemorrhage is > 70% of the lesion;

11. Subfoveal fibrosis or atrophy in the study eye;

12. History of hypersensitivity or allergy to fluorescein;

13. Inability to obtain fundus photographs, fluorescein angiograms or OCT¡¦s of sufficient quality to be analyzed and graded by the Central Reading Centre;

14. Systemic disease with a life expectancy shorter than the duration of the study;

15. Inability to adhere to the protocol with regard to injection and follow-up visits;

16. Legally incompetent adult;

17. Refusal to give written informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2009
Enrollment:	306
Type:	Actual

Ethics review

Positive opinion

Date:	10-03-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1621
NTR-old	NTR1704
Other	MEC AMC : 08-047
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A