Anti-VEGF (bevacizumab/ranibizumab) versus RPE-choroid graft in the treatment of 1) non-responders to 3 intravitreal anti-VEGF injections, or 2) patients with AMD and pigment epithelium rip, or 3) patients with AMD and massive haemorrhage. A randomized trial.

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To compare visual outcome and foveal function after (initiation of) treatment between patients receiving an RPE-choroid graft and patients with anti-VEGF medication.

Ethical review	Approved WMO
Status	Completed
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON33994

Source
ToetsingOnline

Brief title
Anti-VEGF versus RPE-choroid graft

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym

age-relatede macular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis.

Intervention

Keyword: Age-related macular degeneration, Anti-VEGF, RPE-choroid graft

Outcome measures

Primary outcome

Visual acuity, reading vision and foveal fixation at 1 years.

Secondary outcome

VA and reading vision at 2 years.

IOP.

Study description

Background summary

Standard treatment for patients with exudative age-related macular degeneration (AMD) is intravitreal injection of anti-VEGF. Because alternatives are not available, at present, also those patients for whom this therapy probably does not help to improve prospects are initially treated with anti-VEGF. Recently, however, it has been shown that a retinal pigment epithelium (RPE)-choroid graft translocation in the treatment of patients with choroidal neovascular lesions of AMD can stabilize or even improve visual acuity. In this study, it will be investigated whether RPE-choroid graft translocation provides a better alternative to anti-VEGF medication for AMD patients for whom prospects are rather poor otherwise.

Study objective

To compare visual outcome and foveal function after (initiation of) treatment

between patients receiving an RPE-choroid graft and patients with anti-VEGF medication.

Study design

Prospective, international multicenter, randomized intervention study.

Intervention

Arm 1: RPE-choroid graft translocation. Arm 2: intravitreal anti-VEGF (Avastin or Lucentis) injections (PrONTO protocol). Irrespective of study arm, blood will always be surgically removed in patients with massive haemorrhage.

Study burden and risks

Prognosis for exudative AMD complicated by RPE-rip or massive haemorrhage, and for non-responders to anti-VEGF therapy, is very poor. At this moment the only available alternative option for treatment may be an RPE-choroid graft translocation. It has been shown that with this technique vision loss can be limited.
The RPE-choroid graft arm requires two surgical procedures (local or general anaesthesia), i.e. one for the translocation procedure and a second to remove silicone oil. Complications consist of retinal detachment (8%), recurrence of CNV (13%) and haemorrhage (10%).
Massive haemorrhage will always be surgically removed (arm 1: in combination with the first surgical procedure, i.e. the RPE-choroid graft; in arm 2: as single surgical procedure). The risk of complications of haemorrhage removal alone (arm 2) will be less than in combination with the transplantation part.
The anti-VEGF arm receives intravitreal injections (topical anaesthesia) in accordance with the PrONTO protocol. Most patients will receive an injection once every two or three months. Repeated intravitreal anti-VEGF injections pose a (cumulative) risk for endophthalmitis. Each injection is associated with a risk of 0.1% to develop endophthalmitis.
Number of visits during year 1 will be 11 (arm 1) and 8 (arm 2) respectively.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
NL
Scientific

Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- informed consent
- age >= 65 years
- AMD in combination with either of the following conditions:
1 visual loss of >= 15 letters on the ETDRS chart after 3 anti-VEGF injections,
2 subfoveal RPE-tear,
3 massive submacular haemorrhage.
- visual acuity of 20/63 to 20/800.
- recent (< 3 months) activity of the lesion
- myopia < -8 D
- clear media to permit fundus photography, FAG, ICG-A and OCT
- capable to follow instructions
- anticoagulant drugs can be discontinued during 6 weeks

Exclusion criteria

- haemorrhage or PED secondary to:
1 retinal angiomatous proliferation,
2 aneurysm,
3 CNV associated with high myopia,
4 polypoidal choriodopathy.
- hypersensitivity to humanized monoclonal antibodies

- current acute ocular or peri-ocular infection
- any major surgical procedure (scheduled) within 1 month of study entry not related to this study, cataract surgery excepted.
- serious allergy to fluorescein or indocyanine green dye
- significant other ocular disorders affecting visual acuity
- immunocompromised
- current treatment for active systemic infection

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-10-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Avastin
Generic name:	bevacizumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Lucentis
Generic name:	ranibizumab

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-12-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-03-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29614
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2008-008259-41-NL
CCMO	NL26302.078.08