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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Visual outcome in patients receiving RPE-choroid graft will be better than in patients receiving anti-VEGF medication.

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

Summary

ID

NL-OMON29614

Source
NTR

Brief title
N/A

Health condition

Exudative age-related macular degeneration in combination with either 1) visual loss of ¡Ý 15 letters on the ETDRS chart after 3 anti-VEGF injections, 2) subfoveal RPE-tear, or 3) massive submacular haemorrhage.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Visual acuity (lines lost or gained on ETDRS chart) at one year after initial treatment;
2. Foveal fixation;
3. Reading vision (in Austria, Germany and The Netherlands, the Radner chart will be used; in France and Italy the Parinaud chart; in London Jaeger chart) at one year.

Secondary outcome

1. VA at 2 years;
2. Reading vision at 2 years;
3. IOP.

Study description

Background summary

Rationale:
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.
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.
Study population:
Patients with exudative AMD, aged 65 years or older, 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.
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.
Main study parameters:
Visual acuity, reading vision and foveal fixation at 1 and 2 years.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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 protocol24. 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.

Study objective

Visual outcome in patients receiving RPE-choroid graft will be better than in patients receiving anti-VEGF medication.

Study design

Baseline, 12 months, 24 months.

Intervention

RPE-choroid graft, intravitreal anti-VEGF injection.

Contacts

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Eligibility criteria

Inclusion criteria

1. Informed consent;
2. Age > 65 years;
3. AMD in combination with either of the following conditions:
A. Visual loss of > 15 letters on the ETDRS chart after 3 anti-VEGF injections;
B. Subfoveal RPE-tear;
C. Massive submacular haemorrhage;
D. Visual acuity of 20/63 to 20/800.
4. History or examination must indicate recent (< 3 months) activity of the lesion;
5. Myopia < -8 D;
6. Clear media to permit fundus photography, FAG, ICG-A and OCT;
7. Capable to follow instructions;
8. Willing and physically able to complete study visits during at least 12 months;
9. Anticoagulant drugs (Coumarin, antiplatelet agents) can be discontinued during 6 weeks.

Exclusion criteria

1. Haemorrhage or PED secondary to:
A. Retinal angiomatous proliferation;
B. Aneurysm;
C. CNV associated with high myopia;
D. Polypoidal choriodopathy;
E. Known hypersensitivity to humanized monoclonal antibodies;
F. Current acute ocular or peri-ocular infection;

G. Any major surgical procedure (scheduled) within 1 month of study entry not related to this study, cataract surgery excepted.
2. Known serious allergy to fluorescein or indocyanine green dye;
3. Significant other ocular disorders affecting visual acuity;
4. Immunocompromised;
5. Current treatment for active systemic infection.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	240
Type:	Actual

Ethics review

Positive opinion

Date:	20-04-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33994

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1667
NTR-old	NTR1768
CCMO	NL26302.078.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33994

Study results

Summary results
van Zeeburg EJ, Maaijwee K, van Meurs JC. There is no relation

between the occurrence of proliferative vitreoretinopathy and the

location of the donor site after transplantation of a free autologous retinal

pigment epithelium-choroid graft. Acta Ophthalmol. 2014; 92(3): 228-

231. PMID: 23890210