Switching to aflibercept in patients with neovascular AMD not responding to anti-VEGF treatment.

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To examine features of treatment response on optical coherence tomography in patients who were switched to aflibercept after non-response to previous intravitreal anti-VEGF treatment.

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

Summary

ID

NL-OMON38763

Source
ToetsingOnline

Brief title
Switching non-responders to aflibercept.

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
age-related macular degeneration, macular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Bayer

Intervention

Keyword: Aflibercept, age-related macular degeneration, neovascualrization

Outcome measures

Primary outcome

Change in central retinal thickness (µm) as measured on OCT between inclusion and one month after the 3 monthly aflibercept injections.

Secondary outcome

Secondary endpoints are change in visual acuity between inclusion and one month after the 3 monthly aflibercept injections, number of patients responding to aflibercept defined as a decrease in CRT of >50µm from inclusion compared to the last visit and number of patients gaining >5 letters of vision from inclusion compared to the last visit.

Study description

Background summary

Since several years, anti-VEGF agents have become available for the treatment of neovascular age-related macular degeneration (AMD) and have substantially improved visual prognosis in patients suffering from this condition. The anti-VEGF agent used most frequently world-wide is bevacizumab (Avastin). The effectiveness and working mechanism of bevacizumab in comparable to ranibizumab (Lucentis). Even though many patients have benefitted from these anti-VEGF agents, still 10% of patients do not respond to treatment and experience a loss of vision comparable to the natural course of AMD. These patients are considered non-responders. Currently, when patients do not respond to bevacizumab, patients often switch to ranibizumab, which has a comparable working mechanism. Switching to ranibizumab has so far yielded little additional effect. Recently, a new VEGF-inhibitor aflibercept (Eylea) has arrived, with a different mechanism of action. Patients that do not respond to other anti-VEGF agents, may show a good response to aflibercept.

Study objective

To examine features of treatment response on optical coherence tomography in patients who were switched to aflibercept after non-response to previous intravitreal anti-VEGF treatment.

Study design

Prospective interventional case series pilot study.

Intervention

Patients will be treated with 3 monthly intravitreal injections of 2mg (0,05mL) aflibercept.

Study burden and risks

During inclusion patients receive an ophthalmic examinatiom and visual acuity measurement. A fluorescein angiography (FA) and OCT-scan will be performed to confirm the diagnosis of active neovascular AMD. The FA requires intravenous access to administer the fluorescein dye. After inclusion patients are scheduled to receive 3 intravitreal injections with aflibercept with 4 week intervals performed by a trained physician. The first injection will take place within 2 weeks after inclusion. Before the second and third injection an OCT-scan and ophthalmic examination is performed as an additional insurance of safety. One month after the last injection patients will return for an evaluation visit which includes an OCT-scan, visual acuity measurements and ophthalmic examination. Risks in the course of this study are related to receiving intravitreal injections. Serious adverse events are comparable to other intravitreal anti-VEGF injections, namely endophthalmitis, retinal detachment, increased intraocular pressure and a potentially increased risk of thromboembolic events. However, patients may also profit from this study, as they get the opportunity to receive treatment that may prove to be beneficial, especially since other treatment had not been effective.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with neovascular age-related macular degeneration (AMD) that have shown inadequate response to anti-VEGF treatment, defined as a persistant central retinal thickness on optical coherence tomography (OCT) of >=300 µm combined with a response of no greater than a reduction of 50 µm after each previous intravitreal anti-VEGF treatment.;- Patients will have received at least 6 anti-VEGF injections within 1 year. ;- Active neovascular AMD seen as leakage on fluoresceine angiography and (sub-) retinal fluid on OCT. ;- Maximally 1 year since onset of visual complaints and start of anti-VEGF treatment. ;- Minimally 1 month and maximally 3 months between last anti-VEGF injection and first aflibercept injection. ;- Age 50 years and older;- Visual acuity at baseline between 20/25 and 20/320 (Snellen). ;- OCT available prior to first injection and after every three anti-VEGF injections.;- Give written informed consent.

Exclusion criteria

- Signs of subretinal fibrosis, scarring or geographic atrophy on OCT or FA, involving the center of the macula.;- Pigment epithelial detachment with a height of >=150µm. ;- Any ocular diseases beside AMD in the study eye, including myopic fundus and vitreoretinal traction. ;- Myopia of 8.00 D or more, irrespective of myopic fundus features. ;- Ocular surgery of the study eye <= 2 months prior to or during the previous anti-VEGF treatment.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	eylea
Generic name:	aflibercept
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	17-05-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-01-2014

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 19994
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-001208-12-NL
CCMO	NL44122.091.13
OMON	NL-OMON19994