Overstappen op aflibercept bij patiënten die niet reageren op anti-VEGF therapie

No registrations found.

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

Summary

ID

NL-OMON19994

Source
Nationaal Trial Register

Brief title
N/A

Health condition

neovascular age-related macular degeneration, natte leeftijdsgebonden maculadegeneratie

Sponsors and support

Primary sponsor: Prof. Dr. C.B. Hoyng
Radboud University Nijmegen Medical Centre, Ophthalmology Department
Source(s) of monetary or material Support: Bayer B.V.

Intervention

Outcome measures

Primary outcome

Change in central retinal thickness as measured on OCT between inclusion and one month after 3 monthly aflibercept injections

Secondary outcome

- Change in visual acuity between inclusion and one month after 3 monthly aflibercept injections.

- Number of patients responding to aflibercept defined as a decrease in CRT of >50¦Ìm from inclusion compared to visit 5.

- Number of patients gaining >5 letters of vision from inclusion compared to visit 5.

Study description

Background summary

Currently, when patients with neovascular age-related macular degeneration (AMD) do not respond to bevacizumab, patients often switch to ranibizumab, which has a comparable working mechanism. Switching to ranibizumab has so far yielded limited 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.
This prospective interventional case series pilot study will inlcude 20 patients with neovascular AMD who did not respond to previous anti-VEGF therapy defined as: persistant central retinal thickness on optical coherence tomography (OCT) of ¡Ý300 ¦Ìm combined with a response of no greater than a reduction of 50 ¦Ìm after each previous intravitreal anti-VEGF treatment. Patients will be treated with 3 monthly intravitreal injections of 2mg (0,05mL) aflibercept. The primary outcome is change in central retinal thickness (¦Ìm) as measured on OCT between inclusion and one month after the 3 monthly aflibercept injections.

Study objective

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 is 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 limited 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 design

month 0: baseline + first injection

month 1: second injection

month 2: third injection

month 3: evaluation

Intervention

3 intravitreal injections of 2mg (0,05mL) aflibercept with monthly intervals

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with inadequate response to prior anti-VEGF treatment defined as a persistent central retinal thickness (CRT) of ¡Ý300 ¦Ìm combined with a response of no greater than a reduction of 50 ¦Ìm in CRT on OCT 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 FA 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 ¡Ý150¦Ìm.

- 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 ¡Ü 2 months prior to or during the previous anti-VEGF treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2013
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion
Date: 25-09-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38763
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3974
NTR-old	NTR4188
CCMO	NL44122.091.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38763

Study results

Summary results
N/A