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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19994

Bron
NTR

Verkorte titel
N/A

Aandoening

neovascular age-related macular degeneration, natte leeftijdsgebonden maculadegeneratie

Ondersteuning

Primaire sponsor: Prof. Dr. C.B. Hoyng
Radboud University Nijmegen Medical Centre, Ophthalmology Department
Overige ondersteuning: Bayer B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in central retinal thickness as measured on OCT between inclusion and one month

after 3 monthly aflibercept injections

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

month 0: baseline + first injection

month 1: second injection

month 2: third injection

month 3: evaluation

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-09-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38763
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A