Targeted fluorescence imaging using bevacizumab-800CW within Age-related Macular Degeneration (AMD) patients to evaluate the upregulation of VEGF

Published: 11-05-2022
Last updated: 30-11-2024

To determine the safety and feasibility of fluorescence imaging of the eye vascularization with the fluorescent tracer bevacizumab-800CW for identification of neovascular Age-related Macular Degeneration (AMD) with scanning laser angiography.

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

Summary

ID

NL-OMON52066

Source
ToetsingOnline

Brief title
Targeted fluorescence imaging in AMD

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
age related macula degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: PPP project,Tracer BV

Intervention

Keyword: AMD, bevacizumab, macula degeneration, VEGF

Outcome measures

Primary outcome

The measured fluorescence intensity by observing the uptake in retinal, choroid and neovascular tissue.

Safety evaluation of vital parameters, adverse events (AE), serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR);

Secondary outcome

• The optimal dose of bevacizumab-800CW in AMD patients

• The correlation between the fluorescence intensity, target-to-background ratio (TBR) and the disease subtype and severity.

• The difference in uptake between bevacizumab-800CW and vedolizumab-800CW.

• The correlation between the VEGF expression within the tear and the fluorescence signal

Study description

Background summary

Age-related Macular Degeneration (AMD) is an eye disease that destroys the macula, the part of the eye that provides sharp, central vision. It is the third leading cause of blindness. 'Dry' AMD is the most common form, but we are mainly interested in 'wet' AMD. In this type overexpression of VEGF-A causes neovascularization and thereby progression of the disease. These patients are treated with intravitreal anti-VEGF-A injections, though progression is still observed.
With injection of the fluorescent tracer bevacizumab-800 CW (anti-VEGF-A) we

might enable a better understanding of the pathophysiology of VEGF mediated retinal diseases and response to anti-VEGF therapy.

Study objective

To determine the safety and feasibility of fluorescence imaging of the eye vascularization with the fluorescent tracer bevacizumab-800CW for identification of neovascular Age-related Macular Degeneration (AMD) with scanning laser angiography.

Study design

The current study is a non-randomized, non-blinded, prospective, single-center feasibility study.

For the AMD-Bevacizumab two times six patients will be included who receive either 4.5 or 15 mg bevacizumab-800CW. After inclusion of these first twelve patients, an interim analysis will be performed to determine the target-to-background (TBR) in the in vivo images. After the interim analysis, either the 4.5 or 15 mg group will be extended to a maximum of 12 patients. If no fluorescence is detected, the study will be closed after the interim analysis.

Additionally, two types of control groups are added. A tracer control group and a disease control group. The first includes patients with neovascular AMD receiving vedolizumab-800CW to verify the specific binding of the tracer. The latter, includes a group of patients who already receives the tracer bevacizumab-800CW but do not have AMD, to verify difference in signal between disease and no-disease. The AMD-Vedolizumab group will consist of six patients receiving only the optimal doses which is established after the interim analysis.

All patients receive standard clinical care followed by study measurements. Patients will receive an extra OCT and fluorescence measurements before, during and until 1 hour after tracer administration. Patients with AMD (both vedolizumab and bevacizumab) will have an additional measurement at 48-96 hours after administration.

Intervention

Patients receive either bevacizumab-800CW or vedolizumab-800CW. On day 0 they receive both a clinical angiography and a study-related angiography. Additionally, after 48-72 hours a second study-related angiography is performed.

Study burden and risks

No additional risks are expected as previously performed studies with the tracers bevacizumab and vedolizumab-800CW did not show any risks. There is some extra time investment of the patient of 4 hours when joining this research.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

4.2 Inclusion criteria (Patient population)
• Patients with naïve neovascular AMD or neovascular AMD suspected of active disease
• Aged >60years old
• Patients can be included if they already receive therapeutic bevacizumab injections for AMD.

Inclusion criteria (Control population)

• Patients with naïve neovascular AMD or neovascular AMD suspected of active disease
• >60 years of age
- Patients can be included if they already receive therapeutic bevacizumab injections for AMD.

Exclusion criteria

4.3 Exclusion criteria (both populations)
A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Eye pathology interfering with retinal imaging
• Patients with psychological diseases or medical issues who are not able to sign informed consent form;
• Concurrent uncontrolled medical conditions;
• Received a different investigational drug within 30 days prior to the dose of bevacizumab-800CW;
• History of infusion reactions to bevacizumab or other monoclonal antibody.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-11-2022
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bevacizumab-800CW
Generic name:	Bevacizumab-800CW
Product type:	Medicine
Brand name:	vedolizumab-800CW
Generic name:	vedolizumab-800CW

Ethics review

Approved WMO Date:	11-05-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-07-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-01-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-003726-74-NL
ClinicalTrials.gov	NCT05262244
CCMO	NL78391.056.22