Comparing the effectiveness and costs of bevacizumab to ranibizumab in patients with retinal vein occlusions

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The goal of the trial is to compare the efficacy and costs of bevacizumab 1.25 mg and ranibizumab 0.5mg given as monthly intravitreal injections over 6 months for the treatment of macular edema secondary to a retinal vein occlusion.

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

Summary

ID

NL-OMON46979

Source
ToetsingOnline

Brief title
BRVO

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Macular edema secondary to a retinal vein occlusion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: bevacizumab, randomized clinical trial, ranibizumab, retinal vein occlusion

Outcome measures

Primary outcome

The primary study parameter is the mean change in best corrected visual acuity

after 6 months compared to baseline.

Secondary outcome

Amongst others:

The proportion of patients with a decrease of the best corrected visual acuity

less than 15 letters on the EDTRS chart at 6 months compared to baseline.

The proportion of patients with a decrease of the best corrected visual avuity

of 15 letters or more on the EDTRS chart at 6 months compared to baseline.

For the full listings we refer to the protocol chapter 7.1 study endpoints

Study description

Background summary

Ranibizumab (Lucentis), a VEGF inhibitor, is registered for the use of intravitreal treatment of age-related macular degeneration (AMD) and meant a breakthrough for the treatment of these patients. Recently, it will also be registered for the intravitreal treatment of macular edema secondary to retinal vein occlusions (RVO). The therapy has also shown good results for this condition.
The comparable product bevacuzimab (Avastin) is registered for the systemic treatment of patients with metastasized colorectal carcinoma but has been used in an off-label setting in ophthalmology for the intravitreal treatment of AMD and macular edema secondary to a retinal vein occlusion.
The treatment with bevacizumab is much cheaper than the treatment with ranibizumab. The efficacy and safety of bevacizumab has been studied in

case-series and internet based patient registries only, but a directly comparative study for this indication has not yet been published. The general impression is that both products are equally effective.

Study objective

The goal of the trial is to compare the efficacy and costs of bevacizumab 1.25 mg and ranibizumab 0.5mg given as monthly intravitreal injections over 6 months for the treatment of macular edema secondary to a retinal vein occlusion.

Study design

It is a comparative, randomised, double masked study.

Intervention

Bevacizumab 1.25 mg and ranibizumab 0.5mg are administered as monthly intravitreal injections for 6 months to patients with macular edema secondary to a retinal vein occlusion.
During the study visual acuity will be measured, safety assessments, optical coherence tomography and fluorescein angiography will be performed and a questionnaire concerning the costs should be filled in.

Study burden and risks

In this trial patients will receive in total 6 intravitreal injections according to a fixed schedule. In the regular treatment in the first 6 months 3-6 injections are administered in a variable schedule depending on the evolution of the disease. Hence in some cases, study patients will receive more injections than in the regular treatment. This is done in order to compare the maximal effect of both products after 6 months. For each intravitreal injection there is a risk of around 0.05% to develop an endophtalmitis; because of the higher increase in number of injections, this risk is slightly higer for study patients than for the regular treament.
Besides there are possibly unkown risks for the ophthalmological treatment with bevacizumab which is not registered for the treatment of macula edema secondary to retinal vein occlusion.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Male or female patients > 18 years of age with recent vision loss due to foveal center-involved ME secondary to branch or central retinal vein occlusion who, in the opinion of the investigator, could have functional benefit from injections with a VEGF antagonist, and who have signed an informed consent.
* BCVA > 24 and < 78 letters in the study eye and, inclusively, using ETDRS- like visual acuity testing charts at a testing distance of 4 meters (approximate Snellen equivalent of 20/32 to 20/320) at screening.
* Mean central subfield thickness > 275 µm from 2 OCT measurements

Exclusion criteria

see also protocol 4.4

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2012
Enrollment:	228
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Avastin
Generic name:	bevacizumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Lucentis
Generic name:	ranibizumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2012

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-03-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2011-003277-29-NL
CCMO	NL35869.018.11