A Phase IIIb, open-label, multi-centre, 12 month study to evaluate the safety, tolerability and efficacy of ranibizumab (0.3 mg) in patients with subfoveal choroidal neovascularization secondary to age-related macular degeneration.

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The primary objective of this study is to estimate the incidence of ocular adverse events in patients with CNV secondary to AMD who receive an individualized treatment with ranibizumab 0,3 mg.

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

Summary

ID

NL-OMON30261

Source
ToetsingOnline

Brief title
SUSTAIN

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
wet age related macula degeneration

Research involving

Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Het onderzoek wordt gefinancierd door de opdrachtgever Novartis Pharma B.V.

Intervention

Keyword: open-label, ranibizumab, subfoveal choroidal neovascularization secondary to age-related macular degeneration

Outcome measures

Primary outcome

Safety: incidence of Grade 3 targeted adverse events over the one year

treatment period.

Secondary outcome

Efficacy: mean change in best corrected visual acuity and retinal thickness and

time to first re-treatment and total number of treatments.

Safety: all other adverse events, heart rate and blood pressure and the results

of the ophthalmic examinations

Study description

Background summary

Age related macula degeneration (AMD) is one of the most important causes of irreversible vision loss in individuals older than 50 years of age. Because the amount of older individuals will continue to grow, AMD will become a bigger problem for the public health in the future.
Usually the treatment of AMD is only possible in a limit amount of cases of subfoveal choroidal neovascularization (CNV) secundairy to AMD. The treatment is considered to be successful if the visual acuity decreases less fast than without treatment. Often it is not possible to improve the visual acuity. With laser treatment the leaking blood vessels are closed en sometimes further

bleedings and deterioration of the eye sight can be prevented. But also in this situation it can not be guaranteed that the effects remain positive. Treatment with radiotherapy is thoroughly examined. At short notice only a limited group of patients with CNV secondiary to AMD react positive on radiotherapy. Photodynamic therapy can be successful in a selective group of patients with CNV secondairy to AMD. With this therapy the leaking blood vessels are treated and worsening of the visual acuity is decreased. At this moment the efficacy of several different compounds that inhibit the grow of new blood vessels are being tested in patients with CNV secondairy to AMD. Ranibizumab is also known to inhibit the grow of new blood vessels.

Study objective

The primary objective of this study is to estimate the incidence of ocular adverse events in patients with CNV secondary to AMD who receive an individualized treatment with ranibizumab 0,3 mg.

Study design

This is phase IIIb, open label, multi-centre study.
The study consists of 2 periods: the screening period of maximal 2 weeks in which is determined if the patient meets all in, - and exclusion criteria, and the treatment period of 12 months. In this treatment period the investigator decides how many visits to the physician are necessary, which examinations have to be done during the visits and how often the patient is treated with ranibizumab, based on the status of the AMD and the adverse events. In total the patient has to visit the physician minimal 7 and maximal 15 times.

Intervention

During the study all patients will be treated with ranibizumab 0,3 mg.

Study burden and risks

During the study all patients are treated with ranibizumab. To prevent eye infections caused by the injections, patients have to administer antibiotics in the eye before and after the injections.
In the beginning of the treatment period the patients will visit the physician on a monthly basis. Later the patients will visit the physician as needed, based on the opinion of the investigator. During these visits several eye examinations are done. There is a chance that the vision might worsen as a result of progression of the AMD, to a side effect of the injection or to other reasons.
There is a remote chance to experience an allergic reaction to ranibizumab, such as skin rash, hives or possibly more serious problems such as breathing

difficulties or shock. An allergic reaction can also cause dry or itchy eyes.

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

1. Male or female patients >50 years of age
2. Diagnosis of active primary or recurrent CNV secondary to AMD, including those with predominantly classic, minimally classic or occult lesions with no classic component
3. The total area of CNV encompassed within the lesion must be > or equal 50% of the total lesion area
4. The total lesion area must be <= 12 disc areas
5. Patients who have a BCVA score between 73 and 24 letters, inclusive, in the study eye using ETDRS-like grading charts
6. Expectation by the investigator that patients will potentially benefit from ranibizumab

treatment

Exclusion criteria

1. Previous treatment with intravitreally or intravenously administered Avastin * (bevacizumab)
2. Laser photocoagulation, treatment with intravitreal steroids, verteporfin photo dynamic therapy (Visudyne®) or pegaptanib sodium (Macugen®) in the study eye within 30 days preceding Day 1
3. Prior treatment in the study eye with external-beam radiation therapy, vitrectomy, or transpupillary thermotherapy.
4. History of surgical intervention in the study eye within two months preceding Day 1
5. Previous participation in any studies of investigational drugs within one month preceding Day 1
6. Concurrent use of systemic anti-VEGF agents
7. Current use of or likely need for systemic medications known to be toxic to the lens, retina or optic nerve.
8. Concomitant use of chronic NSAIDs for more than seven consecutive days or systemic or topical ocular corticosteroids for three or more consecutive days within six months prior to screening) or at any time during the study.
9. Previous treatment with or participation in a clinical trial involving anti angiogenic drugs
10. Ocular disorders in the study eye that may confound interpretation of study results,
11. Concurrent disease in the study eye that could compromise visual acuity or require medical or surgical intervention during the 12-month study period
12. Vitreous hemorrhage or history of rhegmatogenous retinal detachment or macular hole in the study eye
13. Presence of retinal pigment epithelial tear involving the macula in the study eye
14. History of idiopathic or autoimmune-associated uveitis in either eye
15. Active infectious conjunctivitis, keratitis, scleritis or endophthalmitis in either eye.
16. History of glaucoma filtration surgery or corneal surgery
17. Extracapsular extraction of cataract with phacoemulsification within 2 months preceding Day 1, or a history of post-operative complications within the last 12 months preceding Day 1 in the study eye.
18. Uncontrolled glaucoma in the study eye
19. Aphakia or absence of the posterior capsule in the study eye.
20. Spherical equivalent of the refractive error in the study eye demonstrating more than -8 diopters of myopia; for subjects who have undergone prior refractive or cataract surgery in the study eye, the preoperative refractive error in the study eye can not exceed -8 diopters of myopia

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-05-2006
Enrollment:	16
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Lucentis
Generic name:	ranibizumab

Ethics review

Approved WMO Date:	13-06-2006
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2007
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	EUCTR2005-005921-73-NL
CCMO	NL11296.018.06