A 12-month randomized, double-masked, multicenter, phase II study assessing safety and efficacy of Visudyne photodynamic therapy administered in conjunction with Lucentis versus Lucentis monotherapy in patients with subfoveal choroidal neovascularization secondary to age-related macular degeneration

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

Summary

ID

NL-OMON31180

Source
ToetsingOnline

Brief title
MONT BLANC

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
macular degeneration, subfoveal choroidal neovascularization secondary to age-related macular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma

Intervention

Keyword: Age-related, Lucentis, Macular degeneration, Visudyne

Outcome measures

Primary outcome

- Results Best Corrected Visual Acuity test month 12 compared to baseline

- Treatment free interval of at least three months duration at any timepoint

following Month 2

Secondary outcome

- Number of Lucentis retreatments administered over 9 months following the

Month 2 treatment

- Time to first retreatment with Lucentis following month 2.

- Eye assessments, vital signs and adverse events

- Changes in OCT and angiogram outcomes over 12 months

- Mean change in best corrected visual acuity at month 1, 2 and 3

Study description

Background summary

In de western world, also in The Netherlands, age-related macular degeneration is the leading cause of blindness in individuals older than 50 years. With the ongoing growth of this age-group, AMD is likely to become an increasing problem to the public health.

Both Lucentis and Visudyne are approved and registered in The Netherlands for treatment of age-related macular degeneration. In previous clinical trials it was shown that Lucentis can stabilize or improve vision by inhibition of neovascularization. Visudyne has shown to be able to prevent vision loss or stabilize vision by occlusion of neovascular blood vessels. The combination of the two therapies, acting through different modes of action, bears the potential to provide a more convenient and less frequent therapy while maintaining/improving the increase in vision improvement observed with Lucentis monotherapy.

Study objective

Het objectives of the study are to demonstrate that combination therapy of Lucentis and Visudyne is not inferior in effectivity and safety to monotherapy with Lucentis and to investigate whether less Lucentis injections in combination therapy with Visudyne will achieve the same efficacy as Lucentis monotherapy.
The results of this trial may help physicians refine the clinical management of patients wih CNV secondary to age-related AMD.

Study design

In this 12-month, randomized, double-masked phase two trial, patients will be randomised 1:1 to either combination therapy of Lucentis with Visudyne, or Lucentis and sham PDT (placebo).

Intervention

Lucentis: 0.05 ml intravitreal injection once per month during the first three months. Then retreatment occurs based upon the monthly results of the different eye assessments. The minimum interval between two injections is 30 days.
Visudyne: One intraveneus infusion with 15 mg Visudyne in 30 ml 5%-sucrose-solution and application of a cold laser during 83 seconds to activate visudyne in the eye. Then retreatment occurs based upon the monthly results of the different eye assessments. The minimum interval between two

infusions is 90 days.

Study burden and risks

The average duration of a study visit is three hours. During each visit, blood pressure and pulse will be measured and a standard ophthalmologic exam will be performed. At visit 3 and 12 the patient will be asked to complete a questionnaire with 14 questions regarding treatment satisfaction. This will take about 15 minutes per questionnaire. During visits 1, 3, 4, 5, 12 and as needed during the other visits, a color fundus photograph will be taken and a fundus angiogram will be performed. During visits 1, 3, 4, 5, 8, 11, 14 and as needed during the other visits, an Optical coherence tomography (OCT) will be performed.
Ten milliliters of blood will be collected from patients who agree to participate in the pharmacogenetics study. In the future, genetic markers may be found in these blood samples that can show a relationship between the genetic information and mate waarin een patient op de behandeling met Lucentis en Visudyne reageert en bijwerkingen ervaart.
From non-menopausal female patients, 4 ml of blood will be withdrawn once to perform a pregnancy test. The risks of Lucentis and Visudyne treatment to an unborn fetus are unknown and therefore, pregnant women will be excluded from this study.
The side-effects of Lucentis include an increased eye pressure, eye infections and eye inflammations. The eye pressure will be carefully monitored during the trial and treated if necessary. The intravitreal injection procedure will be performed under sterile circumstances and the patient will be asked to use antimicrobial eye drops three days prior to and three days after a Lucentis injection, to lower the chance on infections.
The side effects of Visudyne include back pain, fatigue and photosensitivity reactions. By avoiding bright light for two days after the Visudyne treatment, the chance of experiencing photosensitivity reaction will be reduced.

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

Protocol page 17
- Male or female patients of any race 50 years or older
- Presence of primary active subfoveal CNV secondary to AMD
- Total CNV area more than or equal to 50% of the total lesion area
- Total lesion area must be less than or equal to 5400 microns
- BCVA letter score in study eye between 24 and 73 letters using ETDRS chart at 4 meters distance
- Written and informed consent
- Patients willing and able to comply with study procedures

Exclusion criteria

Protocol page 17, 18 and 19
- Presence of CNV secondary to causes other than AMD
- Presence of hypofluorescent lesions other than CNV greater than 50% of total lesion
- Tear of the retinal pigment epithelium
- Ocular inflammation or infection within 30 days prior to randomization
- Uncontrolled glaucoma
- Prior treatment for neovascular AMD
- History of intraocular surgery
- Hypersensitivity to components of study drugs
- Use of medication that could induce photosensitivity
- Unable to obtain results from study assessments

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-05-2007
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Lucentis
Generic name:	ranibizumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Visudyne
Generic name:	verteporfin
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-03-2007
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-08-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-07-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2006-004172-12-NL
ClinicalTrials.gov	NCT00433017
CCMO	NL16640.042.07