Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients With Neovascular Age-related Macular Degeneration

Published: 22-06-2015
Last updated: 19-04-2024

To evaluate the safety and efficacy of abicipar (2 mg), compared to 0.5 mg ranibizumab in treatment-naïve patients with neovascular AMD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Interventional

Summary

ID

NL-OMON43671

Source
ToetsingOnline

Brief title
Sequoia Study - Allergan

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
Age-related macular degeneration, AMD

Research involving
Human

Sponsors and support

Primary sponsor: Allergan Limited
Source(s) of monetary or material Support: sponsor (Allergan Ltd)

Intervention

Keyword: - abicipar, - age-related macular degeneration (AMD), - efficacy, - safety

Outcome measures

Primary outcome

Percentage of Patients with Best Corrected Visual Acuity (BCVA) Change from

Baseline *15 Letters in the Study Eye at Baseline and Week 52

Secondary outcome

* Change from Baseline in BCVA in the Study Eye at Week 52

* Change from Baseline in Central Retinal Thickness (CRT) in the Study Eye at

Week 52

* Percentage of Patients with a BCVA Gain of *15 Letters in the Study Eye on

the Early Treatment Diabetic Retinopathy Study (ETDRS) Scale at Week 52

* Change from Baseline in the National Eye Institute Visual Functioning

Questionnaire-25 (NEI-VFQ-25) Composite Score at Week 52

Study description

Background summary

Age-related macular degeneration (AMD) is the leading cause of severe vision loss in people over the age of 65 in the United States (US) and other Western countries. Without treatment, neovascular AMD results in severe visual impairment with an average loss of around 4 lines of visual acuity within 2 years of disease onset.

A drawback of current treatments for neovascular AMD treatments is the need to frequently administer intravitreal injections.It would be highly desirable to develop an agent that requires less frequent injections
.

Study objective

To evaluate the safety and efficacy of abicipar (2 mg), compared to 0.5 mg ranibizumab in treatment-naïve patients with neovascular AMD.

Study design

Structure:
Multicenter, randomized, double-masked, parallel-group, active-controlled study

Duration:
104 weeks participation for each patient following randomization

Randomization/Stratification:
Patients will be randomized by region to 3 treatment groups (2Q8, 2Q12, and rQ4). Within each region, allocation to treatment groups will be stratified by the following 3 factors using a ratio of 1:1:1:
* Disease characteristics of the study eye assessed by the investigator at screening and subsequently
confirmed by the central reading center prior to baseline (D1):
o Lesion type of choroidal neovascularization (predominantly classic versus minimally classic or occult)
o Central retinal thickness (CRT) defined as the central 1000 microns from center of fovea (values * 400 *m versus > 400 *m) as measured from the internal limiting membrane to the top of the retinal pigment epithelium
* Best-corrected visual acuity (BCVA) (* 55 letters versus > 55 letters) assessed at baseline (D1)

Intervention

Study Treatment Groups and Dosage/Dose Regimen:
* Treatment group 2Q8: 2 mg abicipar administered at baseline (D1) and weeks 4 and 8, followed by doses at 8-week intervals through week 96
* Treatment group 2Q12: 2 mg abicipar administered at baseline (D1), and weeks 4 and 12, followed by doses at 12-week intervals through week 96

Controls:
* Treatment group rQ4: 0.5 mg ranibizumab administered every 4 weeks through week 96
The treating investigator will administer the masked study medication by intravitreal injection into the study eye at the assigned visits.

Study burden and risks

There are possible side effects and discomforts associated with the procedures and study treatment. Patients may experience some, all, or none of these effects. The possible side effects and discomforts associated with study procedures and study treatment are described in Addendum VI of the patient

Information Leaflet.
There may be side effects or discomforts from the study treatment that are not yet known including worsening of the macular degeneration.

Pregnancy Risks:
If you are pregnant or become pregnant, there may be risks to the foetus which are currently unknown.

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

- Diagnosis of age-related macular degeneration in at least 1 eye
- Best corrected visual acuity of 20/40 to 20/320 in the study eye
- Best corrected visual acuity of 20/200 or better in the non-study eye

Exclusion criteria

- History of vitrectomy, macular surgery, or glaucoma surgery in the study eye
- Cataract or refractive surgery in the study eye within the last 3 months

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):	18-04-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lucentis
Generic name:	ranibizumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	NA
Generic name:	abicipar pegol

Ethics review

Approved WMO Date:	22-06-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-12-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-01-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-11-2017

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-12-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-02-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-05-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2014□004580□20-NL
CCMO	NL52996.091.15