

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

Published: 22-06-2015

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Ocular structural change, deposit and degeneration NEC
<b>Study type</b>	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

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### 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  $\leq 400 \mu\text{m}$  versus  $> 400 \mu\text{m}$ ) as measured from the internal limiting membrane to the top of the retinal pigment epithelium
- \* Best-corrected visual acuity (BCVA) ( $\leq 55$  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

### Public

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### Scientific

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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