Avastin-Injections in Age Related Macular Degeneration: Prospective Study for Optimal Frequency and Follow-up Determination

Published: 24-07-2007
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To determine the optimal patient observation and Avastin injection schedule.

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

Summary

ID

NL-OMON31474

Source
ToetsingOnline

Brief title
Optimal frequency of Avastin injections in ARMD.

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
age-related macular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Het Oogziekenhuis - Prof. Dr. H. J. Flieringa

Intervention

Keyword: Age-Related Macular Degeneration, Avastin

Outcome measures

Primary outcome

Visual acuity at 12 months.

OCT outcomes at 12 months.

Secondary outcome

Endophthalmitis and other side effects frequency.

Study description

Background summary

Age-related macular degeneration (ARMD) results in a deterioration of the central retinal function, and is the leading cause of blindness in people over 50 years of age in Europe and the USA. The wet form of ARMD, with choroidal neovascularization, is more aggressive and may progress more rapidly to blindness. Recently, Lucentis® has been registered for treatment of wet ARMD, but is (as yet) not reimbursed by health care insurance. Avastin® appears to be a cost-effective alternative for Lucentis®, but an optimal injection schedule has not been determined so far. A reduction of the number of injections, without loss of treatment efficacy, would have a number of beneficial effects: a decrease of the risk associated with intravitreal injection (such as endophthalmitis), cost-effectiveness and reduced ophthalmic work-load.

Study objective

To determine the optimal patient observation and Avastin injection schedule.

Study design

Prospective, open-label, randomized.

Intervention

Intravitreal Avastin injection.

Study burden and risks

Avastin appears to be a promising off-label treatment for exudative ARMD and would provide a cheap alternative to Lucentis. It is FDA and EMEA approved for colorectal tumor treatment adjuvans, and has been shown to be safe for intravitreal use in short term animal and human trials. Repeated injections pose a (cumulative) risk of endophthalmitis, but prognosis for untreated exudative ARMD is very poor.

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

- Informed consent

- Endophthalmitis risks have been made clear
- No preference to paritcipate in the Infliximab for ARMD trial
- Age >= 65 years
- Exudative subfoveolar age related macular degeneration
- No significant other ocular disorders affecting visual acuity
- Not immunocompromised
- No allergy for fluorescein or ICG dye injections
- No treatment for ARMD or other retinal problem in the 3 months prior to trial start
- No planned ocular surgery in the first year after trial start

Exclusion criteria

- Use of coumarin-derivatives at the time of inclusion
- Clinical significant CVA or MCI in the 6 months prior to planned inclusion

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2008
Enrollment:	360
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Avastin
Generic name:	Bevacuzimab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-07-2007
Application type:	First submission
Approved WMO Date:	06-12-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-10-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2007-003766-17-NL
CCMO	NL18584.078.07