Comparison of bevacizumab (Avastin) and ranibizumab (Lucentis) in exudative age-related macular degeneration.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21233

Bron
Nationaal Trial Register

Verkorte titel
BRAMD

Aandoening

eye; retina; age-related macular degeneration; choroidal neovascularization; angiogenesis; bevacizumab; ranibizumab; oog; retina; leeftijdsgebonden maculadegeneratie; Lucentis; Avastin

Ondersteuning

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Overige ondersteuning: ZonMw nr. 17088.5606

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the change in best-corrected visual acuity (BCVA) in the study eye from Baseline to Month 12 assessed with ETDRS-like VA charts at an initial distance of four meter.

Toelichting onderzoek

Achtergrond van het onderzoek

The objective of this study is to compare the effectiveness and costs of 1.25 mg of bevacizumab to 0.5 mg ranibizumab, given as monthly intravitreal injections during one year. This will be a randomized, controlled, double masked, clinical trial in 306 patients in five academic trial centres in The Netherlands. The study population consists of patients 60 years of age or higher with primary or recurrent sub- or juxtafoveal CNV secondary to AMD with a total area of CNV of < 12 disc areas and a best corrected visual acuity BCVA score between 78 and 20 letters in the study eye. The primary outcome measure will be the change in best-corrected visual acuity (BCVA) in the study eye from Baseline to Month 12. Secondary outcomes will be amongst others the proportion of patients with a gain of 15 letters or more and/or a BCVA of 20/40 or more at 12 months, and the costs and costs per quality adjusted life-year of the two treatments

Doel van het onderzoek

The primary objective is to demonstrate the non-inferiority of bevacizumab to ranibizumab in the treatment of patients with subfoveal CNV secondary to AMD as determined by the change in best-corrected visual acuity in the study eye from baseline to month 12.

Onderzoeksopzet

1. 4 months;

2. 12 months.

Onderzoeksproduct en/of interventie

The included patient is randomized to receive either 1.25 mg bevacizumab or 0.5 mg ranibizumab.
Both investigational treatments will be administered by monthly intravitreal injection for one

year (12 injections).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients 60 years of age or higher;

2. Patients with primary or recurrent sub-, juxta- or extrafoveal CNV secondary to AMD, including those with RAP, that may benefit from anti-VEGF treatment in the opinion of the investigator;

3. The total area of CNV (including both classic and occult components) encompassed within the lesion must be more or equal to 30% of the total lesion area;

4. The total lesion area should be < 12 disc areas;

5. A best corrected visual acuity (BCVA) score between 78 and 20 letters (approximately

0,63-0,05 Snellen equivalent) in the study eye.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Ocular treatment with anti-angiogenic drugs in the last 2 months or Triamcinolone in the last 6 months;

2. Laser photocoagulation (juxtafoveal or extrafoveal) in the study eye within one month preceding Baseline;

3. Patients with angioid streaks or precursors of CNV in either eye due to other causes, such as ocular histoplasmosis, trauma, or pathologic myopia;

4. Spherical equivalent of refractive error in the study eye demonstrating more than ¡V 8 dioptres of myopia;

5. Cataract extraction within three months preceding Baseline;

6. IOP >25 mm Hg;

7. Active intraocular inflammation in the study eye;

8. Vitreous haemorrhage obscuring view of the posterior pole in the study eye;

9. Presence of a retinal pigment epithelial tear involving the macula in the study eye;

10. Subretinal haemorrhage in the study eye if the size of the haemorrhage is > 70% of the lesion;

11. Subfoveal fibrosis or atrophy in the study eye;

12. History of hypersensitivity or allergy to fluorescein;

13. Inability to obtain fundus photographs, fluorescein angiograms or OCT¡¦s of sufficient quality to be analyzed and graded by the Central Reading Centre;

14. Systemic disease with a life expectancy shorter than the duration of the study;

15. Inability to adhere to the protocol with regard to injection and follow-up visits;

16. Legally incompetent adult;

17. Refusal to give written informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	26-01-2009
Aantal proefpersonen:	306
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1621
NTR-old	NTR1704
Ander register	MEC AMC : 08-047
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A