BRVO.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23545

Bron
NTR

Verkorte titel
BRVO

Aandoening

macular edema secondary to a retinal vein occlusion

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Department of Ophthalmology
Overige ondersteuning: ZonMw,
The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the change in best-corrected visual acuitiy (BCVA) in the study eye from baseline to month 6 assessed with EDTRS-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 cossts of 1.25 mg bevacizumab to 0.5 mg ranibizumab, given as monthly intravitreal injections during 6 months. This will be a randomized, controlled, double masked, clinical trial in 296 patients in 7 academic strial centres in The Netherlands. The study population consists of patients older than 18 years of age with macular edema secondary to a retinal vein occlusion and a best corrected visual acuity (BCVA) score between 78 and 20 letters in thestudy eye. The primary outcome measure will be the change in BCVA in the study eye from baseline to month 6. 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 6 months and the 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 in the treatment of patients with macular edema secondary to a retinal vein occlusion (branch or central) as determined by the change in best-corrected visual acuity in the study eye from baseline to month 6.

Onderzoeksopzet

6 months.

Onderzoeksproduct en/of interventie

The included patient is randomized to receive either 1.25 mg bevacizumab or 0.5mg ranibizumab. Both investigational treatments will be administered by monthly interval for six months (6 injections).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male or female patients > 18 years of age with vision loss due to foveal center-involved ME secondary to branch or central retinal vein occlusion diagnosed within 6 months before study initiation, who have signed an informed consent;

2. BCVA equal or more than 24 and less or equal to 78 letters in the study eye at screening using ETDRS- like visual acuity testing charts at a testing distance of 4 meters (approximate Snellen equivalent of 20/32 to 20/320);

3. Mean central subfield thickness more than 275 micron on 2 OCT measurements.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant including women whose career, lifestyle or sexual orientation precludes intercourse with a male partner and women whose partners have been sterilized by vasectomy or other means, unless they are using two birth control methods. The two methods can be a double barrier method or a barrier method plus a hormonal method. Adequate barrier methods of contraception include: diaphragm, condom (by the partner), intrauterine device (copper or hormonal), sponge or spermicide. Hormonal contraceptives include any marketed contraceptive agent that includes an estrogen and/or a progestational

agent;

2. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive serum pregnancy test (human chorionic gonadotropin > 5 mIU/ml);

3. Inability to comply with study procedures;

4. Active intraocular inflammation (grade trace or above) in either eye at enrolment;

5. Any active infection (e.g., conjunctivitis, keratitis, scleritis, uveitis, endophthalmitis) in either eye at the time of enrolment;

6. History of uveitis in either eye at any time;

7. Structural damage within 600 micron of the center of the macula in the study eye likely to preclude improvement in visual acuity following in the resolution of macular edema, including atrophy of the retinal pigment epithelium, subretinal fibrosis, laser scar(s), epiretinal membrane involving fovea or organized hard exudate plaques;

8. Uncontrolled (neovascular) glaucoma in the study eye at screening. (IOP > 24 mmHg on medication or according to investigator’s judgment);

9. Evidence of vitreomacular traction in the study eye;

10. Patients who are monocular or have a Snellen VA in the non-study eye (fellow-eye) ≤ 1/300 at visit 1;

11. Any intraocular surgery in the study eye within 3 months prior to randomization;

12. Planned medical or surgical intervention during the 6-months study period;

13. Panretinal laser photocoagulation in the study eye within 3 months prior to or during the study;

14. Focal/grid laser photocoagulation in the study eye 3 months prior to study entry;

15. Treatment with anti-angiogenic drugs in the study eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, VEGF-Trap, etc.) within 3 months prior to randomization;

16. Use of other investigational drugs at the time of enrolment, or within 3 months or 5 half-lives from enrolment, whichever is longer;

17. History of intravitreal corticosteroids in study eye within 4 months prior to randomization;

18. Ocular conditions in the study eye that require chronic concomitant therapy with topical ocular or systemically administered corticosteroids;

19. History of stroke or transient ischemic attack (TIA) within 6 months prior to enrolment;

20. History of myocardial infarction within 3 months prior to randomization;

21. Current use of or likely need for systemic medications known to be toxic to the lens, retina or optic nerve, including deferoxamine, chloroquine/hydroxychloroquine (Plaquenil), tamoxifen, phenothiazines and ethambutol;

22. Known hypersensitivity to fluorescein, bevacizumab or ranibizumab or any component thereof or drugs of similar chemical classes;

23. Any type of advanced, severe or unstable disease or its treatment, that may interfere with primary and/or secondary variable evaluations including any medical condition that could be expected to progress, recur, or change to such an extend that it may bias the assessment of the clinical status of the patient to a significant degree or put the patient at special risk;

24. Ocular disorders in the study eye that may confound interpretation of study results, compromise visual acuity or require medical or surgical intervention during the 6 month study period, including cataract, retinal vascular occlusion, retinal detachment, macular hole, or choroidal neovascularisation of any cause (e.g., AMD, ocular histoplasmosis, or pathologic myopia);

25. Prior episode of RVO;

26. Evidence on examination of sight-threatening diabetic retinopathy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart

(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	296
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-01-2012
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	NL3109
NTR-old	NTR3257
Ander register	ZonMw : 171202018
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A