BRDME.

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To compare the effectiveness and costs of 1.25 mg of bevacizumab to 0.5 mg ranibizumab, given as monthly intravitreal injections during 6 months. It is hypothesized that bevacizumab is non-inferior to ranibizumab regarding its effectiveness.

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

Samenvatting

ID

NL-OMON27161

Bron
Nationaal Trial Register

Verkorte titel
BRDME

Aandoening

Leeftijdsgebonden macula degeneratie
Diabetisch retinopathie

Ondersteuning

Overige ondersteuning: ZonMw

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 6 assessed with ETDRS-like VA charts at an initial distance of 4 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 6 months. This will be a randomized, controlled, double masked, clinical trial in 246 patients in seven academic trial centres in The Netherlands. The study population consists of patients 18 years of age or higher with diabetic macular 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 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 and costs per quality adjusted life-year of the two treatments.

Doel van het onderzoek

To compare the effectiveness and costs of 1.25 mg of bevacizumab to 0.5 mg ranibizumab, given as monthly intravitreal injections during 6 months. It is hypothesized that bevacizumab is non-inferior to ranibizumab regarding its effectiveness.

Onderzoeksopzet

At the baseline visit, the patient will sign the informed consent form, and the medical and ophthalmic history will be taken. Within 14 days after randomization the patient receives the first intravitreal injection of the study drug.
During each visit, vital signs (pulse and blood pressure), concomitant medication and adverse events will be recorded. BCVA will be assessed and an OCT examination will be performed prior to the intravitreal injection. The interval between visits is 30 days, ±7 days to allow for flexibility in scheduling. At baseline and 6 months, an ophthalmic exam and fluorescein angiography will be performed. At baseline, 3 and 6 months patients will be asked to complete a short, 16-item questionnaire on health status (EQ-5D), health care resource utilization, and out-of-pocket expenses (shortened Health and Labour questionnaire).

Onderzoeksproduct en/of interventie

1. 1.25 mg of bevacizumab;

2. 0.5 mg ranibizumab.

Given as monthly intravitreal injections during 6 months.

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 who have signed an informed consent;

2. Patients with Type 1 or Type 2 diabetes mellitus (according to American Diabetes Association or World Health Organization (WHO) guidelines) with glycosylated haemoglobin (HbA1c) less than 12.0% at screening (Visit 1). Patients should be on a dietary, exercise and/or pharmacological program for diabetes. Treatment for diabetes must have been stable for at least 2 months;

3. Patients with visual impairment due to DME (within the EDTRS criteria of clinically significant macular edema) in at least one eye, with a central area thickness >275 ìm, who are eligible for anti-VEGF treatment according to the investigator. If both eyes are eligible, the one with the worse visual acuity, as assessed at visit 1, will be selected by the investigator as the study eye;

4. 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 meter (approximate Snellen equivalent of 20/32 to 20/320).

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 + 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 m of the centre 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 glaucoma in the study eye at screening (IOP > 24 mmHg on medication or according to investigator’s judgment);

9. Neovascularization of the iris in the study eye;

10. Evidence of vitreomacular traction in the study eye;

11. Active untreated proliferative diabetic retinopathy in the study eye;

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

13. History of vitrectomy in study eye regardless of time prior to randomization;

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

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

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

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

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

19. History of intravitreal corticosteroids in phakic eye within 18 months prior to randomization or in post-cataract surgery study eye (aphakic or pseudophakic, without damaged posterior capsule) within 4 months prior to randomization;

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

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

22. Renal failure requiring dialysis or renal transplant or renal insufficiency with creatinine levels > 2.0 mg/dl at screening;

23. Blood pressure systolic > 165 mm Hg or diastolic > 105 mmHg at screening and randomization;

24. Hypertension or change in antihypertensive treatment within 1 month preceding randomization;

25. 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;

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

27. 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;

28. Concomitant conditions in the study eye which would, in the opinion of the investigator,

prevent the improvement of visual acuity on study treatment;

29. 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 neovascularization of any cause (e.g., AMD, ocular histoplasmosis, or pathologic myopia).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	246
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-01-2012
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	NL3093
NTR-old	NTR3247
Ander register	ZonMw / METC AMC : 171202019 / 2011_235;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A