Supplementary File S2: Exclusion criteria

Patient compliance/Administrative

1. Women of childbearing 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 sterilised 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 oestrogen 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.

Ocular medical history

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

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

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

7. Structural damage within 0.5 disc diameter of the centre of the macular in the study eye likely to preclude improvement in visual acuity following the resolution of macular oedema, including atrophy of the retinal pigment epithelium, subretinal fibrosis, laser scar(s), epiretinal membrane involving fovea or organised hard exudate plaques.

8. Patients with both, a best-corrected visual acuity (BCVA) score of >73 letters and a central subfield thickness (CSFT) of <300 μm in the study eye.

9. Uncontrolled glaucoma in either eye at screening (intraocular pressure (IOP) >24 mmHg on medication or according to investigator's judgment).

10. Neovascularisation of the iris in either eye.

11. Evidence of vitreomacular traction in the study eye.

12. History of retinal detachment, retinal tear or macular hole in the study eye.

13. Active proliferative diabetic retinopathy in the study eye, i.e. any neovascularisation that progressed within 6 months prior to randomisation.

14. Patients who are monocular or have a BCVA score in the nonstudy eye (fellow eye) ≤24 letters (approximate Snellen equivalent of 20/320) at Visit 1.

Prior ocular treatments

15. Any intraocular surgery in the study eye within 3 months prior to randomisation.

16. History of vitrectomy in study eye regardless of time prior to randomisation.

17. Planned medical or surgical intervention during the 24-month study period.

18. Panretinal laser photocoagulation in the study eye within 6 months prior to randomisation.

19. Focal/grid laser photocoagulation in the study eye within 3 months prior to randomisation.

20. Treatment with antiangiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab or VEGF-Trap) within 3 months prior to randomisation.

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

22. History of intravitreal corticosteroid treatment in phakic study eye.

23. Intravitreal corticosteroids in postcataract surgery study eye (aphakic or pseudophakic, without damaged posterior capsule) within 3 months prior to randomisation.

24. Ocular conditions in the study eye that require chronic concomitant therapy with topical ocular corticosteroids.

25. Intraocular implants except for lenses.

Systemic conditions or treatments

26. History of stroke within 6 months prior to enrolment.

27. Renal failure requiring dialysis or renal transplant or renal insufficiency with creatinine levels >2.0 mg/dL at screening.

28. Untreated diabetes mellitus.

29. Blood pressure systolic >160 mmHg or diastolic >100 mmHg at screening and/or randomisation.

30. Untreated hypertension or change in antihypertensive treatment within 3 months preceding randomisation.

31. Conditions that require chronic concomitant therapy with systemically administered corticosteroids.

32. 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.

33. Known hypersensitivity to fluorescein or ranibizumab or any component thereof or drugs of similar chemical classes.

34. 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 extent that it may bias the assessment of the clinical status of the patient to a significant degree or put the patient at special risk.

Note: Exclusion criteria in RETAIN were similar to the RESTORE and REVEAL studies of ranibizumab in patients with diabetic macular oedema (DME) with respect to systemic conditions or treatments.