Intravitreal Aflibercept for the Treatment of Treatment Resistant Diabetic Macular Oedema

ACTRN12614001307695

Status	RECRUITING
Phase	Phase 4
Sponsor	Andrew Chang
Enrollment	50 participants

Plain Language Summary

This study is testing a drug called aflibercept (injected into the eye) for patients with diabetic macular oedema — a condition where fluid builds up in the back of the eye due to diabetes, causing blurry vision or vision loss. Some patients do not respond well to the usual eye injection treatments. This study will evaluate whether aflibercept can improve vision and reduce swelling in these treatment-resistant cases.

You may be eligible if:
- You are 18 years or older
- You have type 1 or type 2 diabetes
- You have swelling in the central part of your retina (diabetic macular oedema) that has not improved after at least 4 previous anti-VEGF eye injections over at least 6 months
- Your vision in the affected eye is between a Snellen equivalent of 6/6 and 6/60

You may NOT be eligible if:
- You are pregnant or breastfeeding
- You are a pre-menopausal woman not using contraception
- You have had eye surgery, laser treatment, or a vitrectomy recently in that eye
- Your blood sugar is very poorly controlled (HbA1c above 12%)
- You have had a recent stroke or heart attack (within 3 months)
- You have uncontrolled glaucoma or high blood pressure

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (6)

- Ability to provide informed consent and complete study assessments
- Age 18 years or older
- Macular oedema involving in central macula secondary to type 1 or type 2 diabetic mellitus in study eye.
- Best corrected baseline visual acuity between 85-34 letters on early treatment in diabetic retinopathy study (ETDRS) chart (Snellen equivalent 6/6 to 6/60) on study eye
- Presence of central diabetic macular odema (DMO) >300 microns on spectral domain optical coherence tomography (SD-OCT) after at least 4 anti-VEGF (vascular endothelial growth factor) treatments within minimum of 6 months

... and 1 more (see full listing online)

Exclusion (19)

- Pregnancy or lactation
- Premenopausal women not using contraception
- Prior anti-VEGF injection in the study eye within 30 days of baseline
- Prior treatment with triamcinolone in the study eye within 3 months of baseline

- Intraocular surgery in the study eye within 2 months of baseline

... and 14 more (see full listing online)

Locations (1 total)

Sydney Retina Clinic & Day Surgery - Sydney, NSW, Australia