

A phase II, 12 month, randomized, sham-controlled trial of ranibizumab (Lucentis) combined with grid laser compared with laser alone for the treatment of recalcitrant, diabetic macular oedema.

ACTRN12611000063910

Status	RECRUITING
Phase	Phase 2
Sponsor	Novartis
Enrollment	40 participants

Plain Language Summary

Diabetic macular edema (DMO) is a complication of diabetes where fluid builds up in the center of the retina (the back of the eye), causing blurry vision. This study is testing whether combining the drug ranibizumab (Lucentis — an injection into the eye) with laser treatment works better than laser treatment alone for people whose DMO has not improved enough with laser treatment in the past. Researchers are also trying to design a treatment schedule that requires fewer clinic visits and injections than current approaches.

You may be eligible if:

- You are 18 years or older
- You have diabetic macular edema that affects the center of your retina (fovea)
- Your retinal thickness on an OCT scan is greater than 250 microns in the center, or greater than 300 microns around the center
- Your best-corrected vision falls between 6/12 and 6/477 on a standard eye chart
- You have already had at least one full course of laser treatment for your DMO, at least 4 months ago
- Your kidney function is adequate

You may NOT be eligible if:

- You have poor blood flow in the macula (macular ischemia)
- You have untreated new blood vessel growth in the retina or iris
- You have scarring or atrophy under the central retina in the study eye
- You have had vitrectomy surgery in the study eye
- You are pregnant, breastfeeding, or not using reliable birth control (if of childbearing age)
- You have had a stroke or heart attack in the past
- You have a known allergy to ranibizumab
- You have had an anti-VEGF injection within the past 6 weeks

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

Key Eligibility Criteria

Inclusion (6)

- I. Age 18 years or older.
 - I. Diabetic macula oedema involving the fovea.
 - II. OCT central retinal thickness greater than 250 microns or paracentral macular thickness greater than 300um.
 - III. Best-corrected visual acuity (BCVA) of 0.3 to 1.90 logMAR (6/12-6/477 Snellen equivalent) in the study eye.
- <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12611000063910>
You must have had at least one full course of laser treatment for DMO no sooner than 4 months prior to randomisation.

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at anzctr.org.au. Generated by ClinicalTrialsFinder.org.

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

Exclusion (15)

- I. Macular ischaemia on Fundus Fluroscein Angiogram(FFA)
- II. Untreated retinal or iris neovascularization.
- III. Subfoveal fibrosis or atrophy in the study eye.
- IV. History of vitrectomy surgery in the study eye.
- V. History of idiopathic or autoimmune-associated uveitis in either eye.

... and 10 more (see full listing online)

Locations (1 total)

Australia