

Aflibercept for Diabetic Macular Oedema: Outcomes Using a Treat and Extend Protocol

ACTRN12619000963123

Status	RECRUITING
Phase	Phase 4
Sponsor	The Royal Adelaide Hospital
Enrollment	50 participants

Plain Language Summary

Diabetic Macular Oedema (DMO) is a complication of diabetes where fluid builds up in the central part of the retina (the macula), causing blurred vision. Aflibercept is an approved eye injection treatment that reduces this fluid and can help preserve or improve vision. This study is looking at how well aflibercept works when given using a 'treat and extend' approach — where the time between injections is gradually stretched out based on how well your eye is responding.

After three initial monthly injections, your doctor will adjust the schedule to find the longest interval that keeps your condition stable. This mirrors how the treatment is commonly used in Australia and helps researchers understand the best timing for injections.

You may be eligible if you are an adult with Type 1 or 2 diabetes, have DMO affecting the central part of your vision, and have not previously received eye injections or laser treatment for this condition. People with certain other eye problems, recent heart attacks or strokes, or who are pregnant are not eligible.

Key Eligibility Criteria

Inclusion (6)

- Adult patients 18 years or over with a diagnosis of type 1 or 2 diabetes mellitus.
 - Treatment naïve eyes with evidence of centre involving DMO on FFA and OCT.
 - BCVA equal to between 73 (6/9.5) and 24 (6/95) ETDRS letters inclusive.
 - Definite retinal thickening on clinical examination due to DMO involving the central macula.
 - Media clarity, pupillary dilatation and individual cooperation to allow adequate fundus photographs.
- ... and 1 more (see full listing online)

Exclusion (20)

- Previous treatment with an anti-VEGF agent or intravitreal triamcinolone acetate.
 - Active proliferative diabetic retinopathy in the study eye.
 - Neovascularisation of the iris or angle.
 - Previous macular laser or pan retinal photocoagulation treatment within the last 4 months.
 - Maculopathy due to another cause.
- ... and 15 more (see full listing online)

Locations (2 total)

The Royal Adelaide Hospital - Adelaide, SA, Australia
The Queen Elizabeth Hospital - Woodville, SA, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12619000963123>

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.