

# A Randomised Multi-centre Placebo Controlled Trial of Fenofibrate for Treatment of Diabetic Macular Oedema with Economic Evaluation (FORTE Study)

ACTRN12618000592246

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Status	RECRUITING
Sponsor	University of Sydney
Enrollment	392 participants

## Plain Language Summary

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This trial is testing whether fenofibrate — an oral cholesterol-lowering tablet that has shown promise in slowing diabetic eye disease — can reduce swelling at the back of the eye (diabetic macular oedema) in people with Type 2 diabetes. Diabetic macular oedema is a leading cause of vision loss in people with diabetes, and current treatments involve injections into the eye or laser therapy, which carry risks, costs, and discomfort.

Participants will be randomly assigned to take a daily fenofibrate tablet or a placebo alongside their existing eye care for the duration of the study. The main question is whether fenofibrate reduces the swelling and lessens the need for invasive eye injections or laser procedures.

You may be eligible if you are 25 or older, have Type 2 diabetes, and have been diagnosed with diabetic macular oedema on an OCT scan. People who are already taking fenofibrate, are pregnant or planning pregnancy, have other causes of macular swelling, or have had previous treatment for diabetic macular oedema in the last 12 months are not eligible.

## Key Eligibility Criteria

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### Inclusion (3)

- Male or Female patients  $\geq$  25 years at the time of consent.
- Diagnosed with type 2 diabetes
- Diagnosed with DME on SD-OCT.

### Exclusion (6)

- Current use of fenofibrate
- Pregnancy, or intention to become pregnant within the trial period
- Contraindication to fenofibrate use.
- Other causes of macular oedema including epiretinal membrane, vitreomacular traction, retinal vein occlusion, AMD, cataract surgery in the last 6 months.
- Previous treatment for DME in the prior 12 months including focal/grid laser, anti-VEGF injections, intravitreal triamcinolone injections.

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

## Locations (1 total)

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NSW, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618000592246>

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