

A Pivotal Phase 3 Study of the Efficacy and Safety of DMX-200 in Patients With focal segmental glomerulosclerosis (FSGS) Who Are Receiving an angiotensin II receptor blocker (ARB)

ACTRN12622000066785

Status	RECRUITING
Phase	Phase 3
Sponsor	Dimerix Bioscience Pty Ltd
Enrollment	286 participants

Plain Language Summary

Focal segmental glomerulosclerosis (FSGS) is a serious kidney disease where parts of the kidney's filtering units become scarred, causing significant protein to leak into the urine and, over time, kidney function to decline. It is a leading cause of kidney failure requiring dialysis or transplant. Currently there are limited effective treatments. This Phase 3 trial is testing a new oral medication called DMX-200 in adults and adolescents with FSGS.

DMX-200 is taken twice daily alongside an existing blood pressure and kidney-protective medication called an angiotensin II receptor blocker (ARB). Participants are randomly assigned to receive either DMX-200 or a placebo for up to 104 weeks (about two years), with a possible two-year extension. The main goal is to see whether DMX-200 reduces the amount of protein in the urine — a key indicator of kidney damage — compared to placebo.

You may be eligible if you are aged 12–80, have a confirmed kidney biopsy diagnosis of primary or genetic FSGS, are already taking or willing to start an ARB medication, and have significant proteinuria (protein in urine). People with secondary FSGS, active cancer, heart failure, or who are on immunosuppressive therapies are not eligible. This is one of the few trials offering a potential new treatment pathway for FSGS, a condition with very few effective options.

Key Eligibility Criteria

Inclusion (21)

- DOUBLE BLIND PERIOD
- Patients must be 12 to 80 years old.
- A diagnosis of primary FSGS, genetic FSGS, or FSGS of undetermined cause. Confirmed by kidney biopsy within 7 years of screening.
- Must be either receiving an ARB at the maximal tolerated dose or willing to transition.
- If taking corticosteroids, the dosage must be less than or equal to 10mg / day prednisone (or equivalent) and stable for greater than or equal to 4 weeks prior to and during both Screening and Stabilization, and there must be no plan to change their corticosteroid treatment regimen during the study. Use of inhaled corticosteroids for respiratory diseases is allowed.

... and 16 more (see full listing online)

Exclusion (22)

- DOUBLE-BLIND PERIOD
- Has FSGS secondary to another condition.
- Patients with nephrotic syndrome (greater than 3.5 g/day proteinuria and serum albumin less than 30 g/L) who have not previously been treated with standard of care FSGS-directed therapies (including steroids).
- History of type 1 diabetes mellitus, or uncontrolled type 2 diabetes mellitus (defined as glycated hemoglobin [HbA1c] greater than 8% at Screening)
- History of lymphoma, leukemia, or any active malignancy within the past 2 years (except for basal cell or squamous cell carcinomas of the skin or cervical carcinoma in situ that have been resected and with no evidence of metastatic disease).

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000066785>
... and 17 more (see full listing online)

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.

Locations (20 total)

Brazil

Denmark

France

... and 17 more locations