

TRI-ME: Trimetazidine to treat Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A double-blind, randomised, placebo-controlled efficacy trial

ACTRN12625000095460

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Deakin University
Enrollment	126 participants

Plain Language Summary

Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (ME/CFS) is a serious, long-term illness causing profound fatigue that is made worse by activity, unrefreshing sleep, cognitive difficulties (brain fog), and post-exertional malaise. Despite affecting hundreds of thousands of Australians, ME/CFS has no approved treatments, and current management is largely focused on symptom management rather than addressing the underlying biology of the condition.

This study is trialling trimetazidine — an existing medication approved in Europe and Asia for treating angina (heart pain) — as a potential treatment for ME/CFS. Trimetazidine works by improving how the mitochondria (the 'energy factories' of cells) produce energy, and has anti-inflammatory and antioxidant properties. Participants will take either trimetazidine or a placebo twice daily for 12 weeks and be assessed for changes in fatigue, function, and quality of life.

You may be eligible if you are aged 18 or older, meet the Canadian Consensus Criteria for ME/CFS diagnosis, have a current treating physician, and are willing and able to give informed consent. People with severe kidney disease, Parkinson's disease, restless legs syndrome, current major psychiatric disorders, pregnancy, or who are currently enrolled in another clinical trial would not be eligible.

Key Eligibility Criteria

Inclusion (5)

-) Aged 18 years or above;
-) Fulfil the criteria Canadian Consensus Criteria⁴⁴ for ME/CFS diagnosis;
-) Willing and able to give informed consent prior to study enrolment and to comply with study procedures;
-) Ongoing use of contraception (if sexually active and of childbearing potential age);
-) Nominate a current treating physician.

Exclusion (10)

-) A known or suspected active and unstable systemic medical disorder that is deemed to affect the participant safety to enrol, determined by the PI or their delegate;
 -) Any history of severe renal disease (e.g. eGFR < 30, renal failure), Parkinson's disease, restless legs syndrome or other movement disorders;
 -) A DSM-5 diagnosis of a current major psychiatric disorder (e.g., any of psychotic, bipolar, substance dependence, eating, or significant personality disorders);
 -) Be currently pregnant or breastfeeding;
 -) Have contraindications or intolerance or allergy to trimetazidine;
- ... and 5 more (see full listing online)

Locations (1 total)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625000095460>
VIC, Australia

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