

A Study to Assess TTI-0102 vs Placebo in MELAS Patients

NCT06644534

Status	RECRUITING
Phase	Phase 2
Sponsor	Thiogenesis Therapeutics, Inc.
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (21)

- Patient or Patient's legally designated representative has given written informed consent before any study-related activities are carried out and is able to understand the full nature and purpose of the trial, including possible risks and adverse effects. Patient has provided assent according to local/institutional requirements.
 - Males and females between 16 and 60 years of age at screening.
 - Diagnosis of mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes (MELAS), defined as:
 - \- mtDNA mutation known to be associated with MELAS and MELAS phenotype (Emmanuele et al., 2022) including but not limited to: m.3243A>G, m.13513G>A, m.10191T>C, m. 3271T>C, m. 13136_15374del, m. 8363G>A. Mutation must have heteroplasmy >50% characterized by mutation load in urinary epithelium or blood.
 - AND
- ... and 16 more (see full listing online)

Exclusion (23)

- Documented diagnosis of concurrent inborn errors of metabolism.
 - Non-elective hospitalization related to their mitochondrial disease or direct complication of disease within 60 days prior to the Screening Visit.
 - Overt comorbidity preventing them from safely performing an exercise. In particular, patients suffering from cardiovascular, neurological disorders (e.g. ataxia, sequel blindness from pseudostroke, peripheral neuropathy) or advanced osteo-arthritis.
 - Treatment with taurine during the previous month, and not willing to discontinue for the duration of the trial.
 - Platelet count, lymphocyte count or hemoglobin level below the lower limit of normal (LLN) at screening.
- ... and 18 more (see full listing online)

Locations (2 total)

Angers University Hospital Center (CHU Angers), Angers, France
Radboud University Medical Center, Nijmegen, Netherlands

<https://clinicaltrials.gov/study/NCT06644534>

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