

Low Dose Colchicine in Patients With Peripheral Artery Disease to Address Residual Vascular Risk

NCT04774159

Status	RECRUITING
Phase	Phase 3
Sponsor	Population Health Research Institute
Enrollment	6,150 participants

Key Eligibility Criteria

Inclusion (8)

- Age \geq 18 years
- Symptomatic atherosclerotic LE PAD fulfilling at least one of the following:
 - a. Intermittent claudication with ankle/arm blood pressure ratio* (ABI \leq 0.90) or artery stenosis \geq 50% plus one of i. \geq 1 vascular bed affected by atherosclerosis ii. Diabetes iii. Heart failure iv. Chronic kidney disease (eGFR $<$ 60 mL/min/1.73 m²)
 - b. Rest pain (mostly in foot) OR necrosis of limb OR gangrene of limb (corresponding to either Fontaine stages 3 or 4 OR Rutherford Classification categories 4 to 6). All must have an ankle/arm blood pressure ratio* (ABI \leq 0.90) OR artery stenosis \geq 50%.
- * In cases of incompressible ankle arteries, the presence of toe pressure \geq 60 mm Hg or toe-brachial index \geq 0.70 is acceptable ... and 3 more (see full listing online)

Exclusion (9)

- Contraindication to colchicine
- Long term requirement for colchicine for another clinical indication
- Active diarrhoea
- eGFR $<$ 30 mL/min/1.73 m²
- Cirrhosis or severe chronic liver disease
- ... and 4 more (see full listing online)

Locations (70 total)

Yale School of Medicine, New Haven, Connecticut, United States
University of Florida - Gainesville, Gainesville, Florida, United States
Tampa General Hospital, Tampa, Florida, United States
... and 67 more locations