

# Trial to Assess Chelation Therapy in Critical Limb Ischemia

NCT03982693

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|-------------------|---------------------------------|
| <b>Status</b>     | RECRUITING                      |
| <b>Phase</b>      | Phase 3                         |
| <b>Sponsor</b>    | Mt. Sinai Medical Center, Miami |
| <b>Enrollment</b> | 50 participants                 |

## Key Eligibility Criteria

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### Inclusion (9)

- Age e 50 years
- History of diabetes, defined as medical record evidence or patient report of currently using insulin or oral hypoglycemic agents, or with a history of fasting blood glucose measurement of 126 mg/dL or higher, or a history of HbA1c of 6.5% or higher.
- Significant stenosis (e 75%) of two or more infra-popliteal arteries in the affected limb as verified by at least one imaging technique (angiography, magnetic resonance angiogram, coronary computed tomography angiogram, or doppler examination) within 6 months prior to enrollment;
- History of CLI defined as moderate or high-risk infra-popliteal chronic critical limb ischemia (Rutherford Clinical Severity Score 4 or 5) defined as:
- The presence of rest pain or non-healing ulceration or gangrene for at least 2 weeks plus documentation of severely compromised tissue perfusion:

... and 4 more (see full listing online)

### Exclusion (23)

- <7 days following lower extremity (infra-popliteal), carotid, or coronary revascularization.
- Arterial insufficiency in the lower extremity as the result of a non-atherosclerotic disorder.
- Subjects with evidence of active infection (e.g., cellulitis, osteomyelitis) or deep ulceration exposing bone or tendon or extensive heel ulceration
- Subjects with extensive gangrene extending above the MT joint
- Subjects in whom there is severe pain at rest uncontrollable with pain medications

... and 18 more (see full listing online)

## Locations (1 total)

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Mount Sinai Medical Center, Miami Beach, Florida, United States