

Subclinical Transthyretin Cardiac Amyloidosis in V122I TTR Carriers

NCT05489549

Status	RECRUITING
Sponsor	University of Texas Southwestern Medical Center
Enrollment	500 participants

Key Eligibility Criteria

Inclusion (7)

- (V122I TTR carriers (or matched non-carriers))
 - Men and women ages 30-80 who are V122I TTR carriers (or matched non-carriers) without history of HF (this will be assessed by study personnel) and defined as: a) No history of hospitalization within the previous 12 months for management of HF; b) Without an elevated B-type natriuretic peptide level ≥ 100 pg/mL or NT-proBNP ≥ 360 pg/mL within the previous 12 months; or c) No clinical diagnosis of HF from a treating clinician
 - Signed informed consent
 - Men and women ages 30-80 who have symptomatic V122I hATTR-CA as determined by a history of HF (this will be assessed by study personnel) and defined as: a) History of hospitalization within the previous 12 months for management of HF; b) An elevated B-type natriuretic peptide level ≥ 100 pg/mL or NT-proBNP ≥ 360 pg/mL within the previous 12 months; or c) A clinical diagnosis of HF from a treating clinician.
 - Have an established or suspected diagnosis of hATTR-CA based on either a) Biopsy confirmed by Congo red (or equivalent) staining with tissue typing with immunohistochemistry or mass spectrometric analysis or immunoelectron microscopy, OR b) positive technetium-99m (99mTc)-pyrophosphate or -bisphosphonate scan, combined with accepted laboratory criteria without abnormal M-protein.
- ... and 2 more (see full listing online)

Exclusion (15)

- A self-reported history or clinical history of HF
 - Other known causes of cardiomyopathy
 - History of light-chain cardiac amyloidosis
 - Prior type 1 myocardial infarction (non-ST segment elevation myocardial infarction {NSTEMI} or ST-elevation myocardial infarction {STEMI})
 - Cardiac transplantation
- ... and 10 more (see full listing online)

Locations (3 total)

Columbia University Medical Center, New York, New York, United States
Cleveland Clinic, Cleveland, Ohio, United States
University of Texas Southwestern Medical Center, Dallas, Texas, United States