CLEOPATTRA: A Research Study to Look at the Effects of Treatment With a Medicine Called Coramitug (NNC6019-0001) in People With Heart Failure Due to Transthyretin Amyloid (ATTR) Amyloidosis

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Male or female. * Age 18 years or above at the time of signing the informed consent. * Have an established diagnosis of ATTR-CM (wild-type ATTR \[ATTRwt\] or variant ATTR \[ATTRv\]), with cardiac amyloid infiltration, increased left ventricular (LV) wall thickness, and HF. Note: Target ATTRv recruitment is approximately 15 percent of the study population. 1. Cardiac amyloid infiltration demonstrated by: * Cardiac biopsy positive for TTR amyloid, OR * Grade 2 or 3 cardiac uptake at pyrophosphate (PYP)/diphosphono-1,2-propanodicarboxylic acid (DPD)/ hydroxymethylene diphosphonate (HMDP) scintigraphy with single-photon emission computed tomography (SPECT/CT) combined with an extracardiac biopsy positive for TTR amyloid, OR * Grade 2 or 3 cardiac uptake at PYP/DPD/HMDP scintigraphy with SPECT/CT combined with normal serum free light chain ratio, and negative serum and urine protein electrophoresis with immunofixation (SPIE \& UPIE). Notes: * Non-invasive diagnostic pathway will be confirmed by a centralised expert review. * Bone tracer scintigraphy will be conducted using 99m-technetium (Tc)-labelled pyrophosphate (99mTc-PYP), 99mTc-labelled 3,3-diphosphono-1,2-propanodicarboxylic acid (99mTc-DPD), or 99mTc-labeled hydroxymethylene diphosphonate (99mTc-HMDP). 2. Increased LV wall thickness, as assessed by centralised review of echocardiography, showing interventricular septal wall thickness greater than or equal to 12 millimeter (mm). 3. Chronic HF (New York Heart Association \[NYHA\] Class I-IV) requiring ongoing treatment with a loop diuretic with: * At least 1 documented hospitalisation for HF, OR * History of HF manifested by signs or symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath, signs of pulmonary congestion on x-ray or auscultation, or peripheral oedema). * Expected to be on stable cardiovascular medical therapy (defined as no greater than 50 percent dose adjustment and no categorical changes of medications), with the exception of diuretics, 4 weeks prior to the randomisation visit. * Completed more than 50 meters on the 6MWT at screening.

Exclusion Criteria:

* Known or suspected hypersensitivity to study intervention(s) or related products. * Current or previous participation (dosing with active treatment) in a study for an investigational ATTR depleting drug or ATTR gene editing therapy. * Total bilirubin greater than 3 times the upper limit of normal (ULN) at screening. * Current diagnosis or history of amyloid light chain, other non-ATTR amyloidosis, known leptomeningeal amyloidosis, or multiple myeloma. * HF not primarily caused by ATTR-CM (e.g., due to hypertension, valvular heart disease, or ischemic heart disease in the opinion of the investigator). * Currently hospitalised or hospitalised within 14 days prior to screening. * Currently treated with positive inotropic medication. * Uncorrected, severe, haemodynamically significant, left-sided heart valve disease. Note: Pre-existing echocardiogram up to 2 years old may be used. * Acute coronary syndrome, unstable angina, stroke, transient ischemic attack, coronary revascularisation, cardiac device implantation, cardiac valve repair, or major surgery within 60 days of screening. * Prior solid organ transplant or planned solid organ transplant during the study. * Left ventricular ejection fraction (LVEF) less than 30 percent as assessed by centralised review of echocardiography. * Presence or history of malignant neoplasm (other than basal or squamous cell skin cancer, in situ carcinomas of the cervix, carcinoma in situ/high-grade prostatic intraepithelial neoplasia \[PIN\], low-risk prostate cancer, or on stable therapy for prostate cancer) within 3 years before screening. * End-stage renal disease (estimated glomerular filtration rate \[eGFR\] less than 15 mL/min/1.73 m\^2 at screening, or chronic/intermittent haemodialysis or peritoneal dialysis).

Conditions & Interventions

Interventions:
DRUG: NNC6019-0001, DRUG: Placebo (NNC6019-0001)
Conditions:
Transthyretin Amyloid Cardiomyopathy (ATTR CM)

More Information

Contact(s): Novo Nordisk - clinicaltrials@novonordisk.com
Principal Investigator:
IRB
Number:
System ID: NCT07207811
