cardio TTRansform

About the CARDIO-TTRansform Clinical Trial

CARDIO-TTRansform (ClinicalTrials.gov NCT04136171, EudraCT number 2019-002835-27) is a phase III, multicenter, double-blind study in up to 750 participants with a history of heart failure due to cardiac amyloidosis (ATTR-CM), who will be randomized to receive subcutaneous injections of either eplontersen (45 mg) or placebo once every 4 weeks, receiving available standard of care (SoC). The study consists of a 120-week treatment period. Primary efficacy endpoint is the composite of cardiovascular (CV) mortality and recurrent CV clinical events at Week 120 study visit using the Andersen-Gill method. Participants will also receive daily supplemental doses of the recommended daily allowance of vitamin A.

Does your patient have ATTR-CM?

The CARDIO-TTRansform study is currently enrolling people living with amyloidosis to evaluate the safety and efficacy of eplontersen, an investigational antisense RNA-targeted therapy for people living with hereditary and wild-type ATTR-CM.

Clinical Trial Goal

To evaluate the safety and efficacy of eplontersen compared to placebo for 120 weeks in patients with ATTR-CM receiving available SoC in reducing cardiomyopathy symptoms, improving quality of life, and decreasing the level of the disease-causing protein TTR.

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INCLUSION CRITERIA

- Diagnosis of ATTR-CM by biopsy or positive PYP/DPD/HMDP scan, interventricular septum thickness >12mm, NT-proBNP >600 pg/mL, NYHA class I-III and 6-minute walk distance (6MWD) >150 m.
- Concomitant treatment with tafamidis as SoC for ATTR-CM is allowed.
- Amyloid deposits in cardiac or non-cardiac tissue confirmed by Congo Red (or equivalent) staining OR technetium scintigraphy (99mTc -3,3-diphosphono-1,2-propanodicarboxylic acid [DPD-Tc], 99m Tc-pyrophosphate [PYP-Tc], or 99m Tc-hydroxymethylene-diphosphonate [HMDP-Tc]) with Grade 2 or 3 cardiac uptake in the absence of abnormal light chains ratio, centrally confirmed.
- Females must be non-pregnant and non-lactating, and either surgically sterile or post-menopausal or abstinent. If engaged in sexual relations of child-bearing potential, agree to use 1 highly effective contraceptive method.
- Males must be surgically sterile or, abstinent or, if engaged in sexual relations with a woman of child-bearing potential, the participant or the participant's non-pregnant female partner must be using a highly effective contraceptive method.

EXCLUSION CRITERIA

- Platelet count < 125 × 109/L and urine protein/creatinine ratio ≥ 750 mg/g.
- Acute coronary syndrome, unstable angina, stroke, transient ischemic attack (TIA), coronary revascularization, cardiac device implantation, cardiac valve repair, or major surgery within 3 months of Screening.
- Cardiomyopathy not primarily caused by ATTR-CM, for example, cardiomyopathy due to hypertension, valvular heart disease, or ischemic heart disease.
- Monoclonal gammopathy of undetermined significance (MGUS) and/or immunoglobulin free light chain ratio < 0.26 and > 1.65, unless fat, bone marrow, or heart biopsy confirming the absence of light chain by mass spectrometry or immunoelectron microscopy.
- Prior liver or heart transplant, and/or Left Ventricular Assist Device (LVAD) or anticipated liver transplant or LVAD within 1 year after randomization.
- Current or previous treatment with Tegsedi™ (inotersen) or Onpattro™ (patisiran) or other oligonucleotide or RNA therapeutic (including siRNA).
- Current treatment with diflunisal, doxycycline, and/or calcium-channel blocker. Participants receiving any of these agents must respect a wash-out period of 14 days before randomization.

If you know of or have patients that may benefit from joining the CARDIO-TTRansform study, please contact us at **ionisNCT04136171study@clinicaltrialmedia.com** or **(844) 413-0219.** We look forward to hearing from you and working with you throughout this trial.

ClinicalTrial.Gov Identifier: NCT04136171

For complete list of inclusion/exclusion criteria please see ClinicalTrials.gov NCT04136171