

Acoramidis Transthyretin Amyloidosis Prevention Trial in the Young (ACT-EARLY) Study in Asymptomatic Carriers of a Pathogenic TTR Variant

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Male or female ≥ 18 to ≤ 75 years of age inclusive. * Participants must have an established genotype (hetero- or homozygosity) of a TTR gene variant that is known to be pathogenic (eg, V30M/p.V50M, V122I/p.V142I, T60A/p.T80A, or any other pathogenic TTR variant(s)) confirmed by central laboratory prior to randomization. * Participant's age is no more than 10 years (≤ 10) younger than the PADO. Key

Exclusion Criteria:

* Evidence of ATTR-CM or ATTR-PN. * Presence of a TTR variant known to be phenotypically protective (eg, T119M, R104H). * Current or past treatment with other TTR modifying therapies. * Contraindication to or inability to undergo Cardiac magnetic resonance testing. * Major organ dysfunction, including: kidney disease, liver disease, heart disease (including cardiomyopathy), neuropathy * Other diseases or conditions such as cancer within 3 years, untreated hyperthyroidism or hypothyroidism, type 1 diabetes, active hepatitis B or C, HIV. * Major surgery within the past 3 months or planned during the next 12 months. * Known hypersensitivity to acoramidis.

Conditions & Interventions

Interventions:

DRUG: Acoramidis, DRUG: Placebo oral tablet

Conditions:

Amyloidosis, Amyloid Cardiomyopathy, Transthyretin Amyloidosis, Cardiomyopathies, Heart Diseases, Polyneuropathies

Keywords:

Amyloidosis, ATTR-CM, ATTR-PN, Transthyretin, Amyloid, TTR

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06563895

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