ConTTRibute: A Global Observational Multicenter Long-Term Study of Patients with Transthyretin (TTR)-Mediated Amyloidosis (ATTR amyloidosis)

First published: 10/01/2025

Last updated: 07/05/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000381

EU PAS number

EUPAS1000000381

Study ID

1000000381

DARWIN EU® study

No

Study countries

- [ ] Brazil
- [ ] Bulgaria
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Israel
- [ ] Italy
- [ ] Netherlands
- [ ] Portugal
- [ ] Spain
- [ ] Taiwan
- [ ] United States

Study description

The purpose of this study is to:

- Describe epidemiological and clinical characteristics, natural history and real-world clinical management of ATTR amyloidosis patients
- Characterize the safety and effectiveness of patisiran and vutrisiran as part of routine clinical practice in the real-world clinical setting
- Describe disease emergence/progression in pre-symptomatic carriers of a known disease-causing transthyretin (TTR) variant

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Study status

Ongoing

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Karien Verhulst

Study contact

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Primary lead investigator

Emily Brouwer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/09/2020

Study start date

Actual: 23/11/2020

Date of final study report

Planned: 01/09/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alnylam

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

ALN-TTRSC02-013, NCT04561518

Link to ClinicalTrials.gov

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Study design:

This is a prospective, global, multicenter, long-term observational study designed to document the clinical outcomes of patients with hATTR amyloidosis, or wtATTR amyloidosis, and the safety of patisiran and vutrisiran when used in patients with hATTR amyloidosis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Onpattro, Amvuttra

Study drug International non-proprietary name (INN) or common name

PATISIRAN

VUTRISIRAN SODIUM

Anatomical Therapeutic Chemical (ATC) code

(N07XX12) patisiran

patisiran

(N07XX18) vutrisiran

vutrisiran

Medical condition to be studied

Acquired ATTR amyloidosis

Additional medical condition(s)

Hereditary neuropathic amyloidosis, Amyloidosis, Cardiac amyloidosis, Transthyretin-mediated amyloidosis, Hereditary transthyretin-mediated (hATTR) amyloidosis

Population studied

Short description of the study population

Patients with a diagnosis of ATTR amyloidosis, hereditary or wild type, and pre-symptomatic carriers with a known disease-causing TTR variant will be eligible for the study.

Study design details

Outcomes

The outcomes of interest are incidence of adverse events (AEs), selected events of interest, health care provider reported outcomes and patient-reported outcomes.

Data analysis plan

No statistical inferences will be drawn from the study. Descriptive statistics will be used to meet the objectives of the study.

Data management

Data sources

Data source(s), other

Prospective patient-based data collection

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No