

AMYLO-STUDY - Prevalence of Transthyretin Amyloidosis in Hypertrophic Cardiomyopathy

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General

Identification

Detailed name Prevalence of Transthyretin Amyloidosis in Hypertrophic Cardiomyopathy

Sign or acronym AMYLO-STUDY

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

CNIL

General Aspects

Medical area Cardiology

Health determinants Genetic

Keywords heredity, under-diagnosis, mutation, prevalence

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Private
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Details	French Cardiology Society.
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Governance of the database

Sponsor(s) or organisation(s) responsible	Société Française de Cardiologie
Organisation status	Private

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Not-repeated cross-sectional studies (except case

control studies)

Database recruitment is carried out by an intermediary

A selection of health institutions and services

Database recruitment is carried out as part of an interventional study

No

Database objective

Main objective

To define the prevalence of TTR amyloidosis in a large population of patients attending the CMH.

Inclusion criteria

- Aged 18 years and over;
- Cardiomyopathy defined by an ultrasound thickness of the left ventricle greater than or equal to 13 mm if familial form, or greater than or equal to 15 mm if sporadic form;
- Patients with a signed consent authorising the specific blood test for genetic sequencing to look for an abnormal TTR gene.

Exclusion criteria:

- Significant AS (less than or equal to 1cm²);
- Patients with a cardiomyopathy diagnosis (sarcomeric HCM, Fabry disease, etc.) or related already diagnosed.

Patients included in the REMY registry (Hypertrophic Cardiomyopathy Registry) may also be included in the amyloid-STUDY. Inclusion criteria are very similar. Some additional data will need to be completed on the page corresponding to the registry.

Population type

Age

Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)
Great age (80 years and more)

Population covered

Sick population

Gender

Male
Woman

Geography area

National

Detail of the geography area

France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 05/2012

Date of last collection (YYYY or MM/YYYY) 04/2014

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals Objective:260. 298 patients enrolled on 30/04/2014.

Data

Database activity Current data collection

Type of data collected
Clinical data
Declarative data
Paraclinical data
Biological data

Clinical data (detail) Medical registration

Details of collected clinical data Weight, height, macroglossia, monoclonal gammopathy, carpal tunnel surgical history, EMG, dysautonomia, gastroparesis.

Declarative data (detail) Paper self-questionnaire
Face to face interview

Details of collected declarative data Family and personal history, current or completed treatment.

Paraclinical data (detail) Etiology, MRI, ECG, biopsies.

Biological data (detail) BNP, NT-Pro BNP, troponin, CPK, creatinine, haemoglobin, high-sensitivity CRP, iron level, TSH, serum calcium, serum protein electrophoresis, ?-galactosidase A assay, genotyping.

Presence of a biobank Yes

Contents of biobank Whole blood

Details of biobank content Blood.

Health parameters studied

Health event/morbidity
Health event/mortality

Procedures

Data collection method

e-CRF.

Participant monitoring

No

Links to administrative sources

No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)

Contact the scientist in charge.

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only