

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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Organization	Hôpital

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