# ATTR amyloidosis in patients with heart failure with preserved ejection fraction and a cardiac implantable electronic device

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To investigate the prevalence of transthyretin amyloid cardiomyopathy in HFpEF patients with a cardiac implantable electronic device (CIED) such as a pacemaker or Implantable Cardioverter Defibrillator (ICD)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

# Summary

### ID

NL-OMON49286

**Source** ToetsingOnline

Brief title AMYL-VIP-Device study

## Condition

• Cardiac disorders, signs and symptoms NEC

**Synonym** Protein misfolding disease

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Universitair Medisch Centrum Groningen

1 - ATTR amyloidosis in patients with heart failure with preserved ejection fraction ... 7-05-2025

Source(s) of monetary or material Support: Ministerie van OC&W, Pfizer

### Intervention

Keyword: Amyloidosis, CIED, HFpEF, Wild type

### **Outcome measures**

#### **Primary outcome**

The prevalence of ATTR, measured by bone scintigraphy, in HFpEF patients with CIED.

#### Secondary outcome

A) To assess the frequency of (re-)hospitalization of HFpEF patients with a

CIED diagnosed with or without transthyretin amyloid cardiomyopathy.

B) To assess the clinical characteristics of HFpEF patients also diagnosed with transthyretin amyloid cardiomyopathy.

C) To assess the clinical characteristics of HFpEF patients that decrease the

likelihood of the presence of transthyretin amyloid cardiomyopathy.

D) To assess the mortality of HFpEF patients with a CIED diagnosed with or

without transthyretin amyloid cardiomyopathy.

# **Study description**

#### **Background summary**

Transthyretin-derived amyloidosis (ATTR) is a specific cause of heart failure with preserved ejection fraction (HFpEF). The impact of ATTR on HFpEF leads to

2 - ATTR amyloidosis in patients with heart failure with preserved ejection fraction ... 7-05-2025

poorer prognosis. Therefore, screening for ATTR amyloidosis in HFpEF is meaningful. However, the HFpEF population is heterogeneous and the prevalence of ATTR in HFpEF is not definitive established. The prevalence of ATTR in specific HFpEF subgroups may be higher than the overall prevalence of 13%. As heart failure symptoms and advanced conduction disturbances are often observed in ATTR patients, we hypothesise that the prevalence of ATTR in HFpEF patients with conduction disturbances for which pacemaker implantation was needed, is higher than the general HFpEF population.

#### **Study objective**

To investigate the prevalence of transthyretin amyloid cardiomyopathy in HFpEF patients with a cardiac implantable electronic device (CIED) such as a pacemaker or Implantable Cardioverter Defibrillator (ICD)

#### Study design

Single centre, prospective, observational study.

#### Study burden and risks

In bone scintigraphy the tracer 99mTc-HDP is used. It is a minimally invasive procedure, as only the tracer needs to be administered intravenously. A small possibility of an allergic reaction to the tracer is possible. The expected radiation dose from the entire procedure is 4.5 mSv per scan. There is no risk for other people that come in contact with the patient after the scan.

# Contacts

**Public** Universitair Medisch Centrum Groningen

Hanzeplein 1 Groningen 9700RB NL **Scientific** Universitair Medisch Centrum Groningen

Hanzeplein 1 Groningen 9700RB NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Heart failure, NYHA 2 or 3. CIED LVEF > 40% NT-proBNP >400 ng/L sinus rhythm; > 1200 ng/L atrial fibrillation

### **Exclusion criteria**

Unwilling or unable to sign informed consent. Life expectancy < 1 year. Signficant coronary artery disease or myocardial infarction < 3 months

# Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL

4 - ATTR amyloidosis in patients with heart failure with preserved ejection fraction ... 7-05-2025

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2020
Enrollment:	100
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	15-04-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register** CCMO ID NL72578.042.20