Phenotyping young-onset atrial fibrillation patients (Young-AF)

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Primary objective: To compare at baseline the exact phenotypes of patients with young AF with versus without familial AF. Assessment of the phenotype includes clinical characteristics, presence of validated AF risk factors, (electro-)...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON37717

Source
ToetsingOnline

Brief title
Young-AF

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Interuniversitair Cardiologisch Instituut Nederland

Intervention

Keyword: Atrial fibrillation, Biological markers, Phenotype, Risk factors

Outcome measures

Primary outcome

At baseline the exact phenotypes of patients with young AF with versus without familial AF. Assessment of the phenotype includes clinical characteristics, presence of validated AF risk factors, (electro-)echocardiographic abnormalities, presence of vascular abnormalities, endothelial dysfunction and hypercoagulation.

Secondary outcome

I. At baseline differences in the prevalence of of 1) heart failure (systolic and diastolic); 2) stroke, TIA and peripheral embolism; 3) coronary artery disease including myocardial infarction, acute coronary syndrome and documented significant coronary artery disease necessitating treatment; 4) diabetes mellitus; 5) hypertension; 6) renal failure; 7) subclinical hyperthyroidism; 8) obesity; 9) atrial remodeling measured as increase of atrial sizes and reduction of atrial contractility; 10) biomarker profiles associated with atrial remodeling including fibrosis inflammation, dedifferentiation, etc; 11) biomarker profiles associated with vascular abnormalities, endothelial dysfunction and hyperocagulation; 12) Genes associated with phenotypes of young AF with or without a family history.

II. After 1 and 5 years of follow up differences between both groups in the occurrence of 1) heart failure (systolic and diastolic); 2) stroke, TIA and

peripheral embolism; 3) coronary artery disease including myocardial infarction, acute coronary syndrome and documented significant coronary artery disease necessitating treatment; 4) diabetes mellitus; 5) hypertension; 6)renal failure; 7) cardiovascular mortality; 8) bleeding; 9) severe adverse effects of antiarrhythmic drugs; 10) atrial remodeling measured as increase of atrial sizes and reduction of atrial contractility and remodeling as detected with use of body surface mapping; 11) deterioration of left ventricular systolic and diastolic function; 12) progression of AF to persistent or permanent AF; 13) association of cardiovascular morbidity and mortality with atrial remodeling; 14) biomarker profiles associated with occurrence or deterioration of atrial remodeling including fibrosis inflammation, dedifferentiation, etc; 15) biomarker profiles associated with vascular abnormalities, endothelial dysfunction and hypercoagulation; 16) Genes associated with progression of AF.

Study description

Background summary

Atrial fibrillation (AF) is the most common sustained arrhythmia and is associated with significant morbidity and mortality including stroke and heart failure and an impaired quality of life. AF mostly occurs in elderly patients in the presence of underlying disease. In a minority AF may occur on a younger age (< 60 years, *young onset AF*). Sometimes these patients have no detectable mechanisms, i.e. AF occurs in the absence of validated risk factors. A subset of young-onset AF patients has AF on a familial basis. The exact prevalence of AF occurring at an age < 60 is unknown. In addition, it is not known which part of these patients have familial AF. The exact phenotypes (i.e. clinical characteristics) of young AF patients with and without familial AF have never been investigated and is not known whether there are differences between both groups of patients except for the family history. Assessing the exact phenotypes of young AF patients including the presence or absence of familial AF, may eventually improve risk stratification, therapeutic strategies and

outcome in the individual patient, enabling patient-tailored therapy.

Study objective

Primary objective: To compare at baseline the exact phenotypes of patients with young AF with versus without familial AF. Assessment of the phenotype includes clinical characteristics, presence of validated AF risk factors, (electro-)echocardiographic abnormalities, presence of vascular abnormalities, endothelial dysfunction and hypercoagulation.

Study design

This study is a single-center, prospective observational study. Consecutive patients known at our AF clinic with AF onset at age < 60 years will be asked to participate. Within this patient group phenotypical differences between presence or absence of familial AF will be studied (e.g. prevalence of low-risk AF). Matching of cases (familial AF) and controls (non-familial AF) will be performed on age, type of AF, gender and total duration of AF on a 1:3 basis. Detailed information on the family history, clinical risk factors for AF, electro-echocardiography, body surface mapping, vascular and endothelial function tests and blood samples for analysis of circulating biomarkers and genetic markers will be collected during 3 visits to the outpatient clinic (at inclusion and after 1 and 5 years of follow-up). The control group consists of patients with AF without a family history.

Study burden and risks

Patients will be treated according to evidence-based standard care (ESC 2010 AF guidelines). Visits to a research physician or research nurse will be performed at inclusion, and after 1 and 5 years of follow-up. These visits will be combined with routine visits to the outpatient clinic. Extra (study-related) investigations consist of biomarker analyses, body surface mapping, measurements of vascular function and additional measurements during standard-care echocardiography. Participation to this study does not cause any additonal risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-AF onset at age < 60 years;
-Age > 18 years;
-Written informed consent.

Exclusion criteria

- Post-operative AF
- Myocardial infarction, acute coronary syndrome < 1 month before start AF
- AF triggered by acute infectious diseases
- Hyperthyroidism: patients have to be euthyroid for > 3 months before start AF.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2012
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-12-2015
Application type:	Amendment
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	ID
CCMO	NL40504.042.12