Identification of a risk profile to guide atrial fibrillation therapy in patiens with AF

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

Summary

ID

NL-OMON37361

Source
ToetsingOnline

Brief title
Risk stratification in 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: Nederlandse Hartstichting; Interuniversitair Cardiologisch Instituut Nederland

Intervention

Keyword: atrial fibrillation, biomarkers

Outcome measures

Primary outcome

Primary objective:

To assess the risk profile associated with success of rhythm control therapy at 12 months of follow-up, i.e. all of the following: (1) < 1 second AF on ECG; (2) < 30 seconds AF on 24 hour Holter recording and (3) no symptoms of AF.

Co- primary objective: To assess the risk profile associated with success of rhythm control therapy at 60 months of follow-up, i.e. all of the following: (1) < 1 second AF on ECG; (2) < 30 seconds AF on 24 hour Holter recording and (3) no symptoms of AF.

Secondary outcome

1. To assess the risk profile associated with recurrence of (a)symptomatic AF;

2. To assess the risk profile associated with failure of rhythm control therapy, i.e.
persistent or permanent AF after 1 year;

3. To assess the recurrence and/or progression of cardiac remodeling in AF during follow-up
measured with use of echocardiography (atrial sizes, ventricular function);

4. To study pathophysiological mechanisms of AF, e.g. collagen mediated, inflammation mediated AF, or other mechanisms;

5. To assess the risk profile associated with early (< 4 weeks) versus late

(> after 4 weeks)

AF recurrences;

6. To relate risk profiles with cardiovascular morbidity and mortality;

7. To assess the risk profile associated with success of pulmonary vein

ablation;

8. To study differences in clinical outcome between patients presenting at

the emergency

room and outpatient department.

9. To assess differences in clinical characteristics (e.g. severity of

complaints, heart rate

during AF, ventricular function) between patients included in the

emergency department

versus the outpatient clinic.

10. To assess prognostic parameters predicting the occurrence of the combined

endpoint of

heart failure hospitalization or stroke or all-cause mortality in

patients with atrial fibrillation and heart failure.

11. To assess structural and functional changes by echocardiography in patients

with atrial fibrillation and heart

failure and AF.

Study description

Background summary

Atrial fibrillation is the most common arrhythmia: five to nine percent of patients 60 years of age or older are affected.
Atrial fibrillation is responsible for a decreased exercise capacity due to a fast heart rate and decreased cardiac function.
Atrial fibrillation can either be accepted (rate control), or treatment can consist of restoration of normal sinus rhythm
(rhythm control). With regard to prognosis, rate control is not inferior to rhythm control. However, in patients who remain
symptomatic, rhythm control remains therapy of choice. Rhythm control can be achieved through antiarrhythmic
medication and/or electrical cardioversion. Nevertheless, despite rhythm control, atrial fibrillation recurs in 50% to 80% of
patients within one year.
Atrial fibrillation is associated with a large number of known risk factors, such as age or underlying (heart) disease such as
hypertension, cardiac ischemia, and diabetes, and less well-known risk factors such as obesity and alcohol intake.
Important underlying mechanisms in atrial fibrillation consist of fibrosis and inflammation, which occurs both in cardiac
atria and ventricles. Fibrosis and inflammation can be measured in the blood through biomarkers. However, there is still much to be elucidated concerning the measurement of these underlying mechanisms, the present study will add to this knowledge.

Study objective

The objective of this study is to assess the risk profile which represents the degree of changes in the atrial tissue and
which can help predict in which patients rhythm control will be successful.
This risk profile will consist of a combination of
underlying (heart) disease and risk factors, measurements obtained from echocardiograms, and circulating biomarkers. To achieve this patients will be asked for bloodsamples which will be obtained during usual-care venepunctions at inclusion, at 1 year and at 5 years of follow-up (no additonal
venepunctions will be performed). Furthermore patients will be asked for permission to use their clinical information (e.g. echocardiographic parameters) for this study.
Ultimately such a risk profile could be used to guide the type of rhythm control therapy in individual patients with atrial fibrillation.

Study design

Single-center, prospective, observational study. Patients with symptomatic paroxysmal or (long-standing) persistent atrial fibrillation (AF) in whom a

rhythm control strategy is preferred will be asked to participate. Clinical factors, echocardiographic parameters, and blood samples for analysis of circulating biomarkers will be collected. Patients presenting at the emergency room will be compared to patients presenting at the outpatient clinical, not in the setting of an emergency due to severity of complaints.

Study burden and risks

inclusionvisit:
- blood sample for analysis of biomarkers (to be combined with blood sampling for usual care: no additional venepunctions will be performed)

1 year visit:
- blood sample for analysis of biomarkers (to be combined with blood sampling for usual care: no additional venepunctions will be performed)

5 year visit:
- blood sample for analysis of biomarkers (to be combined with blood sampling for usual care: no additional venepunctions will be performed)

These studyprocedures do not cause any specific risks for the participant.

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

- Symptomatic paroxysmal or (long-standing) persistent AF;
- Rhythm control strategy is preferred;
- No contra-indication for oral anticoagulation;
- Age > 18 years;
- Written informed consent.

Exclusion criteria

- Total history of heart failure and/ or of severe valvular disease > 10 years;
- Severe valvular disease;
- Acute coronary syndrome/ myocardial infarction/ percutaneous coronary intervention/ coronary artery bypass surgery within the past one month;
- Post-operative AF.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-01-2013
Application type:	Amendment
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)
Approved WMO Date:	28-06-2017
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	NL38039.042.11