Hypercoagulable Atrial Appendages in atrial fibrillation (AF): a cross sectional pilot study

Published: 24-01-2008
Last updated: 10-05-2024

To investigate if an AF dependent dysbalance of the physiologically most important pro- and antithrombotic proteins, TF and TM respectively, exists in the atrial appendages.

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

Summary

ID

NL-OMON31424

Source
ToetsingOnline

Brief title
Hypercoagulable Atrial Appendages in AF

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atrial appendages, atrial fibrillation, hypercoagulability

Outcome measures

Primary outcome

Degree of TM an TF expression and activity in the atrial appendages

Degree of CML-CEL expression in the atrial appendages

Secondary outcome

Serum CML-CEL values

Skin auto fluorescence values of AGEs

Viral presence in atrial appendages

Atrial appendage proteomics

AF score (representing the electrophysiological tissue properties)

Study description

Background summary

Rationale:
Atrial fibrillation (AF) is the most common arrhythmia of the Western world. The true danger of AF lies in the increased ischemic stroke risk. Clinical observations of ischemic strokes in low risk patients, ischemic strokes despite oral anticoagulation and increased bleeding risk underline the need for an improved understanding of the pathophysiologic mechanism of thrombus formation in AF patients. The influence of one aspect of Virchow*s triad, endothelial dysfunction, has been underexposed in this matter. With very little evidence at hand, we want to analyze the atrial appendages using a broad range of tools. We include studying the presence of so-called advanced glycation endproducts (AGEs), considering their increasing popularity as important players in cardiovascular disease, (cardiac)viruses as well as proteomics and mapping of electrophysiological properties.

Hypotheses

1. AF is associated with atrial (appendage) endothelial changes favouring an ischemic stroke, either by increasing pro-thrombotic protein expression, decreasing anti-thrombotic protein expression or a combination of both.
2. AGEs are increased in the atrial appendages of AF patients and contribute to the increased thromboembolic risk / hypercoagulable state
3. AGEs concentration relates to type of AF

Study objective

To investigate if an AF dependent dysbalance of the physiologically most important pro- and antithrombotic proteins, TF and TM respectively, exists in the atrial appendages.

Study design

Cross-sectional pilot study

Study burden and risks

The risks associated as well as the patients burden are kept to an absolute minumum by, for instance, performing the transesophageal echocardiograms (TEE) while the patient is anesthetised and sample blood during routine blood drawings. The patient is exposed to the risks inherent to vena puncture. Transthoracic echocardiography and skin autofluorescence measurement are almost without risk. TEE can cause temporary (2 days), mild throat irritation. Despite the surgeons expertise a small peroperative controllable bleedingrisk due to LAA removal exists.
It is of the utmost importance to increase our understanding of this complex pathophysiologic state considering its enormous socio-economical burden on society. Since biopsy of the atrial wall is virtually impossible without perforating the structure, subsequently creating a life-threatening situation, surgical removal is the safest way to obtain atrial tissue.

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

Inclusion criteria cases
1. Electrocardiographically established diagnosis of atrial fibrillation
2. Need for thoracic surgery (requiring median sternotomy);Inclusion criteria controls
1. 18 years or older
2. Need for thoracic surgery (requiring median sternotomy)

Exclusion criteria

Exclusion criteria cases
1. No written informed consent
2. Age under 18 years
3. Severe mitral or aortic valve disease
4. Secondary AF
5. Kidney dysfunction (GFR <30 ml/min, estimated by the Cockroft-Gault formula)
6. Use of experimental study medication in past 6 months;Exclusion criteria controls
1. Electrocardiographically established diagnosis of atrial fibrillation
2. Severe mitral or aortic valve disease
3. No written informed consent
4. Kidney dysfunction (GFR <30 ml/min, estimated by the Cockroft-Gault formula)
5. Use of experimental study medication in past 6 months

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-08-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL19786.068.07