Atrial vortex flow by 4D MRI in different stages of atrial remodeling: a pilot study

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To assess whether atrial flow patterns during sinus rhythm in patients with atrial fibrillation differ from healthy controls with sinus rhythm.

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

Summary

ID

NL-OMON46866

Source
ToetsingOnline

Brief title
Left atrial 4D flow

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
arrhythmia, atrial fibrillation, palpitations

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Afdelingsbudget uit CMR corelab activiteiten (onderdeel van Image Analysis Center VUmc).

Intervention

Keyword: 4D MRI, atrial remodeling, cardiovascular magnetic resonance, vortex flow

Outcome measures

Primary outcome

The main outcome of this study will be the presence of atrial vortex flow, vortex properties, and particle traces in the left atrium as visualized and quantified by 4D flow CMR.

Secondary outcome

Secondary endpoints will be left atrial fibrosis as detected by CMR and left atrial function derived from combining the volumetric measurements on CMR with invasive pressure measurements acquired during pulmonary vein isolation(PVI) procedure in patients with paroxysmal/persistent AF.

Study description

Background summary

Atrial fibrillation (AF) increases the risk for thromboembolic events, mainly ischemic stroke. Several mechanisms in AF lead to blood stasis, causing a thromboembolic environment. In patients with AF thrombi are formed, which are washed out to the periphery and the brain. It is conceivable that atrial flow in paroxysmal AF patients is also impaired when in SR. Probable mechanisms include structural remodeling/fibrosis of the left atrium (LA), mechanical discordance of the left atrial appendage (LAA) all leading to altered atrial hemodynamics. Studies using 4-dimensional (4D) cardiac magnetic resonance imaging (CMR) have shown vortical flow patterns in healthy atria. The present study will serve as a pilot to determine differences in atrial flow patterns during SR between patients with paroxysmal AF, persistent AF and healthy volunteers with SR using 4D flow CMR.

Study objective

To assess whether atrial flow patterns during sinus rhythm in patients with

atrial fibrillation differ from healthy controls with sinus rhythm.

Study design

Observational cohort study, cross sectional

Intervention

All participants will undergo a fluid challenge during the CMR exam with intravenous administration of 500ml NaCl 0.9%.
Patients with AF will undergo the same fluid challenge during PVI treatment as well.

Study burden and risks

All patients will undergo CMR with late gadolinium-enhancement and a fluid challenge with intravenous 500ml NaCl 0.9% in 10 min. Atrial fibrillation patients who are already scheduled for PVI, will have additional atrial pressure measurements during PVI before and after a similar fluid challenge. The risks are minimal. Gadolinium is a very safe contrast agent, which is frequently used in clinical practice. Intravenous gadolinium administration may cause minimal injection site reactions (e.g. pain, cold or burning sensation). As with other contrast-agents, anaphylactic-like reactions can occur, although this is very unusual. For safety reasons a medical doctor will be present during the scanning sessions to monitor the patient*s status. Patients with a known (suspected) allergic reaction to gadolinium or severe kidney failure (GFR <30 ml/min/kg) will be excluded.

For healthy volunteers all study elements are extra (MRI scan en echocardiography). For them the burden consists mainly of an investment of their time. The associated risks are neglible (gadolinium contrast agent as described above and intravenous 500ml NaCl 0.9% has no expected side effects/risks).

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

Atrial fibrillation (AF) groups: paroxysmal AF (defined as AF with spontaneous termination within seven days) OR persistent AF (defined as not self-terminating AF lasting more than 7 days, but not permanent AF); scheduled for pulmary vein isolation treatment
Healthy controls: No history of cardiac disease

Exclusion criteria

All subjects: age under 18 or greater than 75 years; clinically significant valvular disease; left ventricular ejection fraction <50%; severe kidney failure (defined as GFR<60 ml/min/kg); electrical cardioversion <6 weeks prior to inclusion; contra-indication for MRI (i.e. implantable devices, claustrophobia, ocular metallic foreign body, metallic brain clips), known contrast allergy (gadolinium)
Additional for AF patients: atrial fibrillation on ECG on the day of MRI exam
Additional for healthy controls: structural heart disease on echocardiography

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2017
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	4D flow MRI
Registration:	No

Ethics review

Approved WMO Date:	05-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL54302.029.15