Simultaneous Endocardial and Epicardial Mapping of Electrical Activity during Atrial Fibrillation to Study the Occurrence and Origin of Complex Fractionated Atrial Electrograms

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1/ To demonstrate endo-epicardial electrical dissociation (EED) in human atrial fibrillation.2/ To investigate whether occurrence of EED contributes to formation of CFAEs.3/ To study the epicardial conduction pattern above areas with endocardial...

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

Summary

ID

NL-OMON38403

Source
ToetsingOnline

Brief title
Endo-Epi mapping of CFAE

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, fibrillation of the muscles of the 2 chambers of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: NWO VIDI RESEARCH GRANT 91786379 to US

Intervention

Keyword: atrial fibrillation, complex fractionated atrial electrograms, endo-eipcardial dissociation

Outcome measures

Primary outcome

• Presence of EED

• Number, width and origin of waves overlaying CFAE areas.

Secondary outcome

• The correlation between EED index and number CFAEs

• Difference of EED index between paroxysmal AF (PAF group) and persistent AF

(AF group)

• Difference of number of CFAEs between paroxysmal AF (PAF group) and

persistent AF (AF group)

• The correlation between CFAE and number and width of fibrillatory waves

• Identification of different types of CFAE

• Correlation of types of CFAE with PAF and AF.

Correlation of the complexity of atrial fibrillation using

invasive and semi-invasive methods.

Study description

Background summary

Atrial Fibrillation (AF) is the most common sustained arrhythmia. The pathophysiological mechanisms leading to onset and perpetuation of AF are still unclear. Recently, our group demonstrated dissociation of electrical activity during AF between the endocardial and epicardial layer of the atria in goats. This endo-epicardial dissociation (EED) leads to AF stabilization by providing more functional surface for fibrillation wavelets to coexist and represents a prerequisite condition for transmural conduction with reactivation of atrial myocardium in the opposing layer of the atrial wall. Demonstration of EED in humans is lacking so far.
On the other hand, new strategies are developed in treatment of AF by radiofrequency (RF) ablation. More and more, areas of Complex Fractionated Atrial Electrograms (CFAEs), supposingly involved in the perpetuation of AF, are targeted. In some clinical studies, CFAE ablation increases the success rate of RF ablation procedures to convert persistent AF to sinus rhythm. However, studies unmasking the origin and true physiological meaning of CFAEs are lacking.

Study objective

1/ To demonstrate endo-epicardial electrical dissociation (EED) in human atrial fibrillation.
2/ To investigate whether occurrence of EED contributes to formation of CFAEs.
3/ To study the epicardial conduction pattern above areas with endocardial CFAEs.

Study design

Prospective non randomized observational study of consecutive patients who undergo AF ablation in the hybrid room.

Study burden and risks

Except extra time to do measurements, there is no additional risk for participants, as well as no individual benefit expected.

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

paroxysmal or persistent AF

Exclusion criteria

Thoracoscopic Redo procedure
Patients who are not will competent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-03-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	28-06-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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	NL36517.068.11