# Endo-Epi mapping of CFAE.

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1. Describe concomittant electrical activation of endocardial and epicardial layers of atrium that have been shown in animal models to be dissociated, and to be involved in the perpetuation of AF; 2. Describe with a density mapping catheter the...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON20144

**Bron**
NTR

**Verkorte titel**
EEmaCFAE

**Aandoening**

Atrial Fibrillation

### Ondersteuning

**Primaire sponsor:** University of Maastricht
Maastricht Universityhospital
**Overige ondersteuning:** French Society of Cardiology
University of Maastricht

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

1. To demonstrate endo-epicardial electrical dissociation (EED) in human atrial fibrillation by recording simultaneously endocardial and epicardial surface;<br>

2. To study epicardial conduction pattern in areas overlaying endocardial CFAE’s.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

Rationale:

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.

Objectives:

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 population:

All will-competent patients admitted to the academic hospital of Maastricht for RF ablation of AF, using the ‘hybrid’approach..

Intervention:

Simultaneous endocardial and epicardial mapping of the right and left atrial free wall will be performed in all patients, in addition to standard procedure, before and after ablation.

Main study parameters/endpoints:

1. To determine the degree of EED by measuring time activation differences between the endocardial electrograms and the corresponding epicardial electrograms;

2. To correlate the degree of dissociation with the occurrence of endocardial and/or epicardial CFAEs;

3. To quantify the AF complexity in the epicardial activation pattern of areas with endocardially recorded CFAEs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

1. There is no direct clinical benefit expected by this observational study for enrolled patients;

2. Simultaneous endo-epicardial mapping will prolong the procedure with 15 minutes and will require introduction of a dedicated probe into the thoracic cavity;

3. An informed consent and completion of a CFR will take place preoperatively.

**Doel van het onderzoek**

1. Describe concomittant electrical activation of endocardial and epicardial layers of atrium that have been shown in animal models to be dissociated, and to be involved in the perpetuation of AF;

2. Describe with a density mapping catheter the electrical pattern of Complex Fractionated Atrial Electrograms (CFAE), that are a target for Radio Frequency (RF) ablation of AF.

**Onderzoeksopzet**

1. Acute study during the ablation procedure;

2. No specific follow up except that routinely carried out for AF ablation in the institution.

**Onderzoeksproduct en/of interventie**

1. To apply a high density mapping catheter (64 poles) on the epicardial side of the atrium, facing the endocardial catheter routinely used for electrophysiological exploration of AF;

2. To compare offline the corresponding tracings.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients who have signed an informed consent and who are admitted for RF ablation of AF in the "hybrid Operating Room" (HOR).

Ablation of AF in HOR require an endocardial and epicardial approach through thoracoscopy, allowing concommittant access to endo and epicardial side of the atrial wall

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients that didn't give their consent;

2. Patients that don't speak Dutch;

3. Patients that are not will competent.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-06-2011 |
| Aantal proefpersonen: | 48 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2707 |
| NTR-old | NTR2845 |
| Ander register | : |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
1. Time course and mechanisms of endo-epicardial electrical dissociation during atrial fibrillation in the goat.<br>
Jens Eckstein, Bart Maesen, Dominik Linz, Stef Zeemering, Arne van Hunnik, Sander Verheule, Maurits Allessie, Ulrich Schotten.<br>
Cardiovascular Research 2011 vol. 89 (4) pp. 816-24.<br>
2. Classifying fractionated electrograms in human atrial fibrillation using monophasic action potentials and activation mapping: evidence for localized drivers, rate acceleration, and nonlocal signal etiologies.<br>
Sanjiv M Narayan, Matthew Wright, Nicolas Derval, Amir Jadidi, Andrei Forclaz, Isabelle Nault, Shinsuke Miyazaki, Frédéric Sacher, Pierre Bordachar, Jacques Clémenty, Pierre Jaïs, Michel Haïssaguerre, Mélèze Hocini.<br>
Heart Rhythm 2011 vol. 8 (2) pp. 244-53.