

De SPECTACLE studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29521

Source

NTR

Brief title

SPECTACLE

Health condition

Atrial fibrillation

Sponsors and support

Primary sponsor: MST Enschede

Source(s) of monetary or material Support: CardioResearch Enschede

Intervention

Outcome measures

Primary outcome

Correlation between speckle tracking determined global strain measurement and percentage of low voltage points in the left atrium.

Secondary outcome

-Recurrence of atrial fibrillation within 12 months after a blanking period of 3 months defined as registration of atrial fibrillation on ECG or episode lasting >30 seconds on Holter/Vitaphone

recording.

-Correlation between strain/strain rate measurements and regional percentage of low voltage in the LA.;

-Correlation between laboratory values and voltage measurements

-Predictive value of strain/strain rate measurements and low voltage percentage for recurrent atrial fibrillation after catheter ablation.

-Quality of life before and after PVI measured with SF-12 questionnaire

Study description

Study objective

We hypothesized that there should be a relationship between LA structural remodeling assessed by invasive voltage mapping in the left atrium and LA functional remodeling assessed by strain and strain rate imaging in patients with AF.

Study design

1 year

Intervention

Measurement of left atrial voltage and echocardiographic strain measurements

Contacts

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Eligibility criteria

Inclusion criteria

- Eligible to undergo percutaneous radiofrequent catheter ablation of atrial fibrillation.
- Sinus rhythm during echocardiography
- Age >18 years
- Expected follow up >12 months

Exclusion criteria

- Previous PVI or MAZE procedure.
- Emphysema
- Unable to provide informed consent.
- Pregnancy
- Presence of pacemaker or ICD

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	21-04-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47852
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5074
NTR-old	NTR5205
CCMO	NL51350.044.15
OMON	NL-OMON47852

Study results