Correlation between speckle tracking determined left atrial strain measurements and voltage mapping in patients with paroxysmal atrial fibrillation undergoing catheter ablation

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Primary objective of this study is to investigate the possible correlation between non-invasive strain(rate) measurements with speckle tracking in the left atrium and invasive voltage measurements in the left atrium. Secondary abjectives are to...

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

Summary

ID

NL-OMON47852

Source
ToetsingOnline

Brief title
SPECTACLE

Condition

- Cardiac arrhythmias

Synonym
AFIB, Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Directe financiering door CardioResearch Enschede

Intervention

Keyword: Atrial Fibrillation, Cardiac, Catheter Ablation, Echocardiography, Electrophysiologic Techniques

Outcome measures

Primary outcome

Correlation between left atrial strain and percentage LA low voltage points

Correlation between left atrial strain rate and percentage LA low voltage

points

Secondary outcome

Recurrence of atrial fibrillation within 12 months defined as registration of

atrial fibrillation on ECG or episode lasting >30 seconds on Holter/Vitaphone

recording (With blanking period of 3 months).

Correlation between left atrial strain and regional left atrial voltage.

Correlation between left atrial strain rate and regional left atrial voltage.

Correlation between serum uric acid and percentage LA low voltage points

Correlation between C-terminal telopeptide van collagen type-I (CITP) and

percentage LA low voltage points

Predictive value of combined left atrial strain/strain rate and mean LA voltage

for recurrent atrial fibrillation after catheter ablation.

Predictive value of left atrial strain/strain rate for recurrent atrial

fibrillation after catheter ablation.

Predictive value of mean LA voltage for recurrent atrial fibrillation after

catheter ablation.

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

Study description

Background summary

Atrial fibrillation(AF) is a chronic progressive disease in which changes occur in structure and function of the left atrium (LA). Structural remodeling is characterized by LA enlargement and interstitial fibrosis, both being predictors of recurrence of AF after pulmonary vein isolation. Despite improvements in technical possibilities there is still a high failure rate of non-farmacological treatment of atrial fibrillation, therefore non-invasive assessment of structural changes by means of speckle tracking in the left atrium could lead to better patient selection. We hypothesized that there should be an 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 objective

Primary objective of this study is to investigate the possible correlation between non-invasive strain(rate) measurements with speckle tracking in the left atrium and invasive voltage measurements in the left atrium. Secondary abjectives are to assess whether correlation exists between regional voltage in the left atrium and strain/strain rate measurements; laboratory values and voltage measurements, recurrence rate, quality of life bofore and after p[rocedure and predictive value of strain/strain rate measurements and voltage measurements for recurrent atrial fibrillation after catheter ablation.

Study design

Single centre correlation study

Study burden and risks

Echocardiographic measurements are non-invasive of nature, additional burden consists of extended measurements during routine echocardiography during several minutes.
Construction of a voltage map is a safe procedure when performed by an experienced operator. this will add 10 minutes to procedure time, which is

acceptable considering total procedure time of approximately 2 tot 3 hours.
Additional laboratory assessments pose no additional burden or 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

Patients > 18 years with paroxysmal atrial fibrillation referred for possible catheter ablation

Exclusion criteria

Unable to provide written informed consent
Unable to undergo echocardiographic evaluation

Previous PVI or MAZE procedure.
Emphysema
Pregnancy
Pacemaker or ICD

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	29-08-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29521
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51350.044.15
Other	Volgt