# Optimization of pulmonary vein isolation by using grid visualization

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To study the effect of grid visualization during PVI on procedure times, to study the effect of grid visualization on acquiring direct isolation after encircling the pulmonary veins (*single round* ), to study the effect of grid visualization on the...

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

## Summary

### ID

NL-OMON46613

**Source**
ToetsingOnline

**Brief title**
OPTIGRID

### Condition

- Cardiac arrhythmias

**Synonym**
A-fib, Atrial fibrillation

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Biosense Webster (a Johnson & Johnson company),Zie G2a

## Intervention

**Keyword:** Atrial fibrillation, Catheter ablation, Grid annotation, Pulmonary vein isolation

## Outcome measures

### Primary outcome

procedure time, defined as time from first RF lesion to last RF lesion. Last RF lesion may be last RF of completion of pulmonary vein encircling combined with direct isolation (single round isolation), last RF for isolation if additional touch-up lesions are necessary or last RF to achieve re-isolation in case of reconnection during the procedure

### Secondary outcome

percentage single round isolation for each PV pair, defined as complete isolation occurring without the need of additional *touch ups*

freedom from atrial arrhythmia at follow-up, defined as atrial fibrillation, atrial flutter or atrial tachycardia demonstrated by a valid ECG tracing obtained after the 90-day post-ablation blanking period

# Study description

### Background summary

Freedom of atrial fibrillation (AF) after pulmonary vein isolation (PVI) is limited to 50-80% of patients, dependent on patient characteristics. This is typically due to electrical reconnection between the pulmonary veins and the left atrium at follow-up. Efforts to optimize outcome of catheter ablation for AF should therefore be directed towards creation of complete and lasting lesion circles.
The Carto3 mapping system allows 3D visualisation of a cardiac chamber by fast anatomical mapping using intracardiac catheters. During PVI, an outline (*shell*) of the left atrium is created on which the location of ablation can be manually annotated.

The new *Visitag* module of the Carto 3D mapping system allows automated visualization of the precise site of ablation using a grid that is displayed on the 3D shell of the mapped cardiac chamber. In addition, it shows the amount of radiofrequency (RF) time for each specific grid point. Displaying the grid may provide a superior visual feedback for the operator on continuity of ablation lines and stability of the catheter, compared to single dot visualization by manual or automatic tagging. As a result it may improve procedure times and outcomes of catheter ablation of atrial fibrillation.

### Study objective

To study the effect of grid visualization during PVI on procedure times, to study the effect of grid visualization on acquiring direct isolation after encircling the pulmonary veins (*single round* ), to study the effect of grid visualization on the 12 month freedom of atrial fibrillation after pulmonary vein isolation, to study Visitag settings that are associated with single round PVI

### Study design

This is a single-center randomized prospective intervention study.

### Intervention

Patients will be randomized to either encircling pulmonary veins using the automated point-by-point annotation (ablation index) or encircling pulmonary veins using the grid annotation.

### Study burden and risks

All patients will receive standard of medical care for PVI including cardiac CT or MRI at baseline and transthoracic echocardiography (TTE), and Holter monitoring at follow-up.
This study is designed to study techniques in PVI of which future patients may benefit.

## 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

All patients (> 18 years) eligible for pulmonary vein isolation according to ESC (European Society of Cardiology) guidelines.

## Exclusion criteria

Unwilling or unable to give written informed consent
Prior left atrial ablation or left atrial flutters
Prior left atrial surgery
Hyperthyroidism (treated hyperthyroidism in euthyriodic state is not an exclusion criterion)
Untreated or uncontrolled hypertension (systolic RR > 160 mmHg)

# Study design

## Design

Study type: Interventional

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|---|---|
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-09-2018 |
| Enrollment: | 88 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Carto3 |
| Registration: | Yes - CE intended use |

## Ethics review

Approved WMO

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|---|---|
| Date: | 17-07-2018 |
| Application type: | First submission |
| 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

ID: 25776
Source: NTR
Title:

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL63859.029.18 |
| OMON | NL-OMON25776 |