

EP Navigator 3D ATG Learning Curve Evaluation

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To document a single centre learning curve to use 3D ATG overlay with catheter position tagging to assist atrial fibrillation ablation procedures. To compare use of 3D ATG overlay and the tagging tool contemporary mapping/localisation tools (Carto or...

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

Summary

ID

NL-OMON32827

Source

ToetsingOnline

Brief title

3D ATG Evaluation

Condition

- Cardiac arrhythmias

Synonym

atrial fibrillation; dysrhythmia of the heart

Research involving

Human

Sponsors and support

Primary sponsor: R&D, cardiologie

Source(s) of monetary or material Support: Philips Healthcare

Intervention

Keyword: Fluoroscopic images, Left atrial anatomy, Rotational X-ray scan

Outcome measures

Primary outcome

Procedural duration, X-ray exposure and acute success of the catheter ablation

Secondary outcome

n.a.

Study description

Background summary

Philips Healthcare has introduced EP navigator with 3D ATG that allows the overlay of a 3D model of the left atrial anatomy on fluoroscopic images to guide atrial fibrillation catheter ablation. This 3D model is generated from a rotational X-ray scan by a Philips Allura XperCT FD 10 system (3D atriography or 3D ATG). This investigation aims at measuring the single site learning curve to use EP navigator and 3D ATG. A secondary aim is to assess whether at the end of the learning curve total procedure time is longer, shorter or equal to ablation procedures guided by means of conventional navigation systems such as Carto and NavX.

Study objective

To document a single centre learning curve to use 3D ATG overlay with catheter position tagging to assist atrial fibrillation ablation procedures.

To compare use of 3D ATG overlay and the tagging tool contemporary mapping/localisation tools (Carto or NacX) to guide atrial fibrillation ablation in terms of procedure time, fluoroscopy time, X-ray dose, contrast dose at the start of the learning curve and at the end of the learning curve of using 3D ATG overlay.

To test the hypothesis that total procedure time when employing 3D ATG is decreasing with the number of procedures to a level comparable or below total procedure time when employing established methods (Carto or NavX).

Study design

This investigation is single site clinical evaluation of existing and approved software. Patients will be randomized to the 3D ATG overlay guided groups and the control group in a 1 to 1 fashion.

Study burden and risks

Increased exposure to X-ray and contrast could occur. In standard procedures 60 ml of contrast is required compared to 100 ml in the 3D ATG group. It is uncertain if any increased X-ray exposure will occur in the 3D ATG group. If, after the learning curve is over, CT-scan can be omitted, 3D ATG will surely reduce overall X-ray exposure. For 3D ATG it is not necessary to introduce additional catheter in the sheaths.

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 with paroxysmal or persistent atrial fibrillation eligible for pulmonary vein isolation according to current guidelines

Exclusion criteria

Patient not willing or able to give consent to participate in the study and/or patients already involved in a clinical trial, and patients with poor renal function who cannot tolerate the amount of contrast medium needed to perform 3D ATG.

Study design

Design

Study type:	Observational invasive
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):	12-01-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO	
Date:	04-01-2010

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL30454.060.09