Comparison between the multi-electrode Octaray and Pentaray catheters in patients undergoing ablation for atrial tachycardia using Coherent Mapping.

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Primary Objective: • To contrast Coherent Mapping quality (electrograms per map) and noise assessment using Octaray (with TRUEREF technology) versus Pentaray catheter for left and right atrium.Secondary Objective(s): • To contrast the Coherent...

Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON53474

Source
ToetsingOnline

Brief title
OCTOPUS-AT

Condition

- Cardiac arrhythmias

Synonym
atrial-flutter, atrial-tachycardia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Biosense Webster, Inc.,Biosense-Webster

Intervention

Keyword: Ablation, Atriumtachycardia, Octaray, Pentaray

Outcome measures

Primary outcome

1) number of electrograms per map;

2) voltage-based signal to noise ratio per map.

Secondary outcome

1) electrograms acquisition rate per map;

2) electrogram acquisition density;

3) number of electrograms acquired per beat;

4) the total ablation and fluoroscopy times per group;

5) acute mapping success per group

6) number of entrainments attempted and best post-pacing interval value at

ablation site per group, when available.

Study description

Background summary

Ablation of atrial tachycardia (AT) remains challenging even in the era of sophisticated 3D mapping systems. Among others far-field signals and noise remains an important issue hampering high-resolution mapping of complex ATs, and adequately mapping AT is a time-consuming process. Possibly, the recently developed Octaray catheter, which utilizes a non-contact central electrode and more closely spaced electrodes may tackle these issues and improve the map efficiency, quality and improve identification of the AT mechanism.

Study objective

Primary Objective:
• To contrast Coherent Mapping quality (electrograms per map) and noise assessment using Octaray (with TRUEREF technology) versus Pentaray catheter for left and right atrium.

Secondary Objective(s):
• To contrast the Coherent Mapping times using Octaray versus Pentaray catheters for left and right atrium.
• To assess whether Octaray is more efficient/effective than Petaray in identifying the critical components of the arrhythmia mechanisms and ablation targets (acute success) using Coherent Mapping.
• To assess the radiofrequency applications/duration and fluoroscopy times in patients with Octaray-based Coherent Mapping versus Pentaray-based Coherent Mapping.

Study design

This is a randomized open-label trial including consecutive patients undergoing ablation for atrial tachycardia of the left and right atrium. Half of the eligible patients will be randomized to undergo Coherent Mapping with Pentaray catheter first followed by Coherent Mapping with the Octaray catheter next. The other half will undergo initial Coherent Mapping with the Octaray catheter followed by Pentaray catheter. All study participants (N=60) will undergo the Coherent Mapping with both catheters. Only the second map created with either Octaray (active arm, N=30) or Pentaray (control arm, N=30) will be used for the subsequent ablation procedure.

Intervention

Additional 3D Coherent map with Octaray catheter on top of the standard Coherent map with Pentaray catheter.

Study burden and risks

The harms of the study are limited. The new catheter (Octaray) has similar shape, is made from similar material and is similar in size as the standard catheter (Pentaray), the only difference is the number of splines and electrodes. The creation of two maps will increase the mapping time, but because of more information provided by two maps, it is possible that the total procedure time is similar or lower due to more precise/efficient ablation. Changing the catheters may in theory increase the chance of air-embolism, however in the hands of experienced operators the risks should be negligibly small and catheter changing during such complex procedures are common practice.

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

Adult patients planned for ablation of atrial tachycardia or atrial flutter.

Exclusion criteria

Individuals not able to provide informed consent for any reason including language and metal disabilities.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-05-2023
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Multi-electrode Octaray 3-D mapping catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-02-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-08-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	05-10-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
Other	Clinicaltrials.gov
CCMO	NL80780.078.22