NorthStar

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To evaluate the accuracy of catheter localization using the NorthStar software during real-time MRI-guided cardiac ablation therapy.

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

Summary

ID

NL-OMON56550

Source
ToetsingOnline

Brief title
NorthStar

Condition

- Cardiac arrhythmias

Synonym
Atrial Arrhythmia, Atrial flutter

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ablation, Flutter, Interventional MRI

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the accuracy of catheter localization using the NorthStar software during real-time MRI-guided cardiac ablation therapy. At the start of the procedure, the catheters will be manoeuvred to the predefined areas within the right side of the heart based on the specific electrical signals in that area. These locations will be virtually marked within the NorthStar software. The extent to which these markers maintain their spatial coordinates after the ablation procedure, evaluated by obtained electrical signals, will serve as a quantitative measure of the system's accuracy.

Secondary outcome

To investigate the influence of additional factors, such as breathing pattern, procedure duration, complications during ablation, and patient characteristics, on the pre- and post-ablation marker distance. This secondary objective will complement the primary objective of evaluating the accuracy of the NorthStar software.

Study description

Background summary

The introduction of real-time MRI-guided cardiac ablation therapy, a significant advancement in interventional medicine, necessitates precise catheter tracking for accurate navigation within the complex cardiac anatomy. The introduction of the NorthStar software as an active tracking system holds promise for improving the precision and efficiency of catheter manipulation during these procedures. However, a rigorous evaluation of its accuracy and

reliability in a clinical setting is crucial to validate its viability.

Study objective

To evaluate the accuracy of catheter localization using the NorthStar software during real-time MRI-guided cardiac ablation therapy.

Study design

The study is a prospective trial involving 20 patients undergoing real-time MRI-guided flutter ablation procedures at Amsterdam UMC. Patient will be informed to participate in the study at least two weeks prior to the procedure by their treating physician and written informed consent will be obtained prior to the ablation procedure. Markers will be strategically positioned in NorthStar at key anatomical points (specific anatomical landmarks), guided by distinct electrical signals. Post-ablation, a re-evaluation of the localization of the (virtual) markers as displayed by NorthStar will be conducted to assess the drift of the projected markers, indicating the accuracy of the system. The ablation procedure will be performed according to current guidelines and applicable regulations.

Intervention

Throughout the real-time MRI-guided ablation procedure, the operator will assess the precision of the NorthStar 3D navigation software. Before commencing the actual ablation, the operator will confirm the alignment of the 3D anatomical shell, generated in NorthStar through specific electrical signals. Post the ablation procedure, a secondary alignment verification will be conducted to detect any potential drift or shift. These alignment tests are anticipated to require only a few minutes.

Study burden and risks

The NorthStar mapping system poses no unique risks in comparison to other mapping systems commonly employed in clinical settings. Potential risks associated with the NorthStar mapping system are related to the interventional devices used with the Mapping system rather than the system itself.

The benefits of this software are not immediately apparent to individual patients participating in the study, although the improved integrated 3D visualization provided by NorthStar can contribute to a more streamlined and efficient treatment process, resulting in a shorter procedural time.

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 undergoing a real-time MRI-guided flutter ablation procedure at the Amsterdam UMC.

Exclusion criteria

Lack of legal capacity.
Insufficient proficiency in the Dutch language.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2024
Enrollment:	20
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	08-02-2024
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL85844.015.23
Other	Pending