The Effect of median Nerve Stimulation On cardiac electRophysiology (TENSOR)

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The primary objective of this pilot study is to examine the impact of MNS on cardiac electrophysiology measured at a high-resolution scale during SR.

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

Summary

ID

NL-OMON57314

Source
ToetsingOnline

Brief title
TENSOR

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial fibrillation, Effect on cardiac electrophysiology, Median nerve stimulation

Outcome measures

Primary outcome

The impact of MNS on cardiac electrophysiological properties, such as the

unipolar potential slope and conduction disorders, measured during SR.

Secondary outcome

None

Study description

Background summary

Mortality, morbidity and health care costs due to atrial fibrillation (AF) are worldwide growing problems and therapeutic interventions for AF are often not effective. For many years, it has been suggested that the autonomic nervous system (ANS) plays an important role in AF pathogenesis. The ANS may either induce remodelling in the atria or undergo remodelling itself, thereby serving as a substrate for AF. Several critical points within the cardiac neural axis serve as targets for therapeutic intervention. Studies have demonstrated the effectiveness of neuromodulation therapy for AF, including low-level vagus nerve stimulation (LLVNS), stellate ganglion block, or ganglionated plexi ablation, in reducing AF inducibility, incidence, and burden. Recently, median nerve stimulation (MNS) has also been found to have antiarrhythmic effects. There is evidence that MNS prevents atrial effective refractory period (AERP) shortening and increased AF inducibility during rapid atrial pacing. A wearable device has been designed for MNS, and preliminary data within the AF population indicate the potential of this device in treating AF.
Previous mapping study indicates that LLVNS affects electrophysiological properties during sinus rhythm (SR). However, the underlying electrophysiological mechanism is unknown.

Study objective

The primary objective of this pilot study is to examine the impact of MNS on cardiac electrophysiology measured at a high-resolution scale during SR.

Study design

This pilot study is designed as an interventional study.

Intervention

High-resolution cardiac mapping during SR

Study burden and risks

Neither the patient, nor the investigators are in any way compensated for their participation with regards to this study. The risks associated with participation are known to be negligible, since epicardial mapping using the non-investigational product (see Medical Device Dossier) in over 1500 patients in previous METC-approved studies (MEC 2010-054, MEC 2014-393, MEC 2015-373, MEC 2019-543, MEC 2020-0124) did not cause any complications. The duration of the surgical procedure is minimally prolonged by the epicardial mapping procedure with an estimate of 8-10 minutes.
Studies in different medical fields have shown that MNS is a safe treatment modality. Patients may benefit from this study as MNS has been shown to prevent AERP shortening and increased AF inducibility during rapid atrial pacing. Moreover, this novel therapy may serve as a treatment of AF in non-surgical patients. At the same time, the device's wearable nature and monitoring capabilities have emerged as key advantages for patients, facilitating treatment and enabling adjustments to care plans.

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

Age equal or older than 18 years
Ischemic heart disease
Scheduled for elective cardiothoracic surgery

Exclusion criteria

Hemodynamic instability
Usage of inotropic agents
Emergency cardiac surgery
Prior left-sided radiation of the chest for malignancies

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-02-2025
Enrollment:	53

Type:	Actual

Medical products/devices used

Generic name:	CardiaCare RR2 median nerve stimulator
Registration:	No

Ethics review

Approved WMO Date:	18-02-2025
Application type:	First submission
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
CCMO	NL87294.078.24