Intensive molecular and electropathological characterization of patientS undergOing atriaL fibrillATion ablatION: a multicenter prospective cohort study

Published: 19-12-2019
Last updated: 15-05-2024

To identify predictors of success of AF ablation including clinical factors, AF recurrence patterns, anatomical and electrophysiological characteristics, circulating biomarkers and individual genetic background.

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

Summary

ID

NL-OMON52886

Source
ToetsingOnline

Brief title
ISOLATION: a multicenter prospective cohort study

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
atrial arrhythmia, Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse Hartstichting en Europese Unie

Intervention

Keyword: Ablation, Atrial fibrillation, Pulmonary Vein Isolation

Outcome measures

Primary outcome

The primary endpoint is ablation success, defined as freedom from documented recurrence of atrial arrhythmia after 12 months. Recurrences in the first 3 months after the index procedure (blanking period) are exempted.
Atrial arrhythmias are defined as AF, atrial tachycardia (AT) and non-isthmus dependent atrial flutter (AFl). Following the current guidelines, episodes of atrial arrhythmia should be documented on ECG, on Holter monitoring (minimum duration of 30 seconds), or on an implanted device (atrial high rate episode during at least 5 minutes or mode switch, and confirmed as being AF or other atrial arrhythmia by a trained physician).

Secondary outcome

• Time to recurrence of atrial arrhythmia after the blanking period.

• Time to recurrence of AF after the blanking period.

• Early AF recurrences, defined as any episode of AF during the blanking period.

• Early recurrences of atrial arrhythmia, defined as any episode of AF, AT or non-isthmus dependent AFl during the blanking period.

• Changes in circulating biomarkers and non-invasive electrophysiological markers for substrate quantification.

• Use of antiarrhythmic drugs (AADs) one year after ablation.

• Redo procedures, defined as repeated ablation procedure with the goal to prevent recurrence of AF or reduce the AF burden after one or more previous attempts to achieve the same goal.

• Number of veins with pulmonary vein reconnection at redo procedure.

• Major adverse cardiovascular events (MACE).

Study description

Background summary

Although ablation is a common step in the treatment for atrial fibrillation (AF), the procedure does not have the intended effect in about one third of patients. Despite several well-known clinical predictors, it remains a challenge to identify patients at risk for ablation failure with satisfactory certainty.

Study objective

To identify predictors of success of AF ablation including clinical factors, AF recurrence patterns, anatomical and electrophysiological characteristics, circulating biomarkers and individual genetic background.

Study design

Prospective cohort study of patients undergoing AF ablation. Clinical characteristics and results of routine tests are collected. In addition, the following (non-standard) tests are performed: extended surface electrocardiogram (extECG), extended rhythm monitoring prior to the ablation, lean body mass index, biomarker testing, genetic analysis, questionnaires. In subgroups of patients transesophageal electrocardiogram (TE-ECG), epicardial electroanatomical mapping and/or left atrial appendage (LAA) biopsy is performed.

Study burden and risks

Participation in this study requires no additional visits to the outpatient clinic. Standard outpatient clinic visits may be prolonged by 10-20 minutes. Extended rhythm monitoring and questionnaires are completed at home, these will

take some additional time as well.
Extended rhythm monitoring and questionnaires are not associated with risks. The extECG might lead to skin irritation due to the additional leads. The blood samples at baseline are collected together with routine clinical blood tests, no additional venipuncture is necessary. Blood samples after 3 and 12 months are taken specifically for the study, these additional venipunctures might be accompanied by hematomas. The LAA biopsy is performed after clipping of the LAA and is not associated with increased risks. The epicardial electroanatomical mapping during hybrid procedures extends the procedure (and thus time on single lung ventilation) with 10-15 minutes.
The TE-ECG is performed in patients from whom additional consent is obtained. The insertion of the TE-ECG probe can be unpleasant for the patient, but serious complications have not been observed until now. Previous studies report complications in 0-1,4% of patients, mostly atrial arrhythmias. The ablation itself is clinically indicated and performed as standard practice following a routine protocol. No specific recommendations for the procedure itself, management and/or treatment after the procedure will be given during this registry.

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

In order to be eligible to participate in this registry, a subject must meet all of the following criteria:
• 18 years of age or older;
• Documented atrial fibrillation;
• Scheduled for AF ablation or redo AF ablation;
• Able and willing to provide written informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this registry:
• Serious patient condition before ablation;
• Emergency procedures.

A subject who meets any of the following criteria will be excluded from the subset in whom additional consent for transesophageal ECG (TE-ECG) is asked:
• Known esophageal disease;
• Previous surgery on esophagus, throat or stomach;
• Recent (<4 weeks) myocardial infarction;
• Unwilling to provide additional informed consent.

Epicardial mapping is only performed in the subset of patients undergoing hybrid ablation or surgical ablation. A subject who meets any of the following criteria will be excluded for this additional procedure:
• COPD Gold II, III, or IV;
• Heart failure, currently in NYHA class III or IV;
• Any other pulmonary, cardiac, or other condition that may compromise a safe conduct of epicardial mapping in the opinion of the treating physician or investigator, taking the prolonged duration of single lung ventilation into account.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-03-2020
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-09-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-11-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	06-04-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 20836
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70787.068.19
Other	NL7894 (Netherlands Trial Register), NCT04342312 (clinicaltrials.gov)
OMON	NL-OMON20836