# ISOLATION: a multicenter prospective cohort study

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON20836

**Source**
NTR

**Brief title**
ISOLATION

**Health condition**

Atrial fibrillation

### Sponsors and support

**Primary sponsor:** Academisch ziekenhuis Maastricht (azM)
**Source(s) of monetary or material Support:** MUMC+

### Intervention

### 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 atrial fibrillation (AF), atrial tachycardia (AT) and non-isthmus dependent atrial flutter (AFl), lasting more than 30 seconds, documented on electrocardiogram (ECG) or Holter monitoring.

**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**

Rationale
Although there are several individual factors which are known to influence the chances of successful atrial fibrillation (AF) ablation, it remains a challenge to identify patients at risk for ablation failure with satisfactory certainty.

Objectives
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 registry 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, 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 population
Patients aged 18 years and older with documented AF, scheduled for AF ablation.

Main study endpoints
Ablation success after 12 and 24 months, defined as freedom from any episode of documented atrial arrhythmia after the blanking period.

### Study objective

It is the aim of this study to establish an integrated risk profile including clinical risk factors, AF recurrence patterns, anatomical and electrophysiological characteristics, circulating biomarkers and individual genetic background, to predict ablation failure after different ablation techniques.

### Study design

Primary endpoint: 12 months after ablation.
Total follow-up duration: 24 months after ablation

## Contacts

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## Eligibility criteria

### 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;
· Physically or mentally unable to provide written informed consent.

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.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 26-01-2020 |
| Enrollment: | 500 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 52886
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL7894 |
| CCMO | NL70787.068.19 |
| OMON | NL-OMON52886 |

# Study results