ISOLATION: a multicenter prospective cohort study

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20836

Bron
NTR

Verkorte titel
ISOLATION

Aandoening

Atrial fibrillation

Ondersteuning

Primaire sponsor: Academisch ziekenhuis Maastricht (azM)
Overige ondersteuning: MUMC+

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Primary endpoint: 12 months after ablation.

Total follow-up duration: 24 months after ablation

Contactpersonen

Publiek

Maastricht UMC+
Dominique Verhaert

024-3092470

Wetenschappelijk

Maastricht UMC+
Dominique Verhaert

024-3092470

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-01-2020
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52886
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten