Defining the BURden after surgical ablation therapY for the treatment of Atrial Fibrillation

Published: 07-07-2016
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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON47756

Source
ToetsingOnline

Brief title
BURY-AF

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: lokaal;dienst CTC

Intervention

Keyword: Atrial fibrillation, Surgical ablation

Outcome measures

Primary outcome

The primary objective of the study is:

- to evaluate the burden of AF and quality of life rhythm after thoracoscopic ablation surgery and after port-access concomitant left atrial MAZE surgery by continuous rhythm monitoring (Medtronic Reveal Linq Insertable Cardiac Monitor*).

Secondary outcome

Secondary objectives are:

- to evaluate freedom from AF/AFl/AT,

- to assess the clinical safety of the procedure

- to assess neurologic outcome (ischemic stroke, hemorrhagic stroke, transient ischemic attack)

- to evaluate the postoperative biochemical cardio-inflammatory response (NT-pro-BNP, CRP, IL-6 and troponin levels)

Study description

Background summary

Rationale: AF recurrences after ablation therapy (surgical and catheter ablation) are common within the first months after AF ablation. The temporarily increased risk of recurrences may be related to atrial edema, local inflammatory response leading to enhanced automaticity or vulnerability of the atrial substrate to AF, increased adrenergic tone and changes in fluid and electrolyte balance. An early recurrence of AF after ablation does not

necessarily indicate long-term ablation failure. Therefore, the definition of 1-year success was stated as freedom from AF/AFL/AT (>30 seconds) off antiarrhythmic drug therapy as assessed from the end of the 3-month blanking period to 12 months following the ablation procedure. This statement is based on literature derived from experience after catheter ablation for AF. It can be speculated that the amount of tissue necrosis after surgical ablation is higher compared to catheter ablation. Consequently, the amount of tissue edema in and around the lines could therefore be more extended and longer lasting. Furthermore, (thoracoscopic) AF surgery results in some degree of post-pericardiotomy syndrome which might be responsible for AF recurrences itself. We hypothesize that the blanking period after (thoracoscopic) surgical ablation might be longer than the arbitrarily chosen 3 months period after AF ablation.
Patients suffering from AF suffer from considerable impairment in quality of life (QoL). One of the main goals of treatment is to restore rhythm to improve symptoms, and to improve quality of life. The current definition of success according to the 2014 HRS statement defines a single recurrent episode of AT/AF/AFl of more than 30 seconds 3 months after ablation as failure while the actual burden and possibly also the quality of life could potentially have been improved significantly.

Study objective

The primary objective of the study is:
- to evaluate the burden of AF and quality of life rhythm after thoracoscopic ablation surgery and after port-access concomitant left atrial MAZE surgery by continuous rhythm monitoring (Medtronic Reveal Linq Insertable Cardiac Monitor*).
Secondary objectives are:
- to evaluate freedom from AF/AFl/AT,
- to assess the clinical safety of the procedure
- to assess neurologic outcome (ischemic stroke, hemorrhagic stroke, transient ischemic attack)
- to evaluate the postoperative biochemical cardio-inflammatory response (NT-pro-BNP, CRP, IL-6 and troponin levels)

Study design

Single-center, prospective observational cohort study

Study burden and risks

There are no risks associated with participation. During hospitalization the blood collection for this study will be performed simultaneously with routine blood collection (2/4). Three months after surgery blood collection will be

performed one more time, simultaneously with a routine visit

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435 cm
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435 cm
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-(Longstanding) persisterend or paroxysmal AF
-Accepted for thoracoscopic surgical ablation (TT-maze or port-access concomitant left atrial MAZE surgery (heartport))
-18 years or older
- The patient is mentally able and willing to give informed consent
- The patient agrees with the implantation of an implantable loop recorder

Exclusion criteria

No ILR implantation prior to surgery

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2019
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-10-2019
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL56551.100.16