A prospective randomized multicentre efficacy study on defining the optimal cryoballoon duration therapy for treatment of atrial fibrillation: The 1-2-3 study

Published: 18-02-2014
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To assess the optimal ablation duration using the second generation cryoballoon for isolation of pulmonary veins in the treatment of atrial fibrillation.

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

Summary

ID

NL-OMON45131

Source
ToetsingOnline

Brief title
The 1-2-3 study

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Directe financiering door CardioResearch Enschede

Intervention

Keyword: Atrial fibrillation, Cryoballoon therapy, Duration, PVI

Outcome measures

Primary outcome

Acute success (=entrance and exitblock) of pulmonary vein isolation.

Secondary outcome

a) (Imminent) complications, defined as:

1. Phrenic nerve palsy or diminishment of diaphragm excursion during

cryo-ablation.

2. Temperatures reaching <12 C in the oesopaghus during cryoablation.

3. Other complications such as delayed gastric emptying, pericardial

fluid/tamponade, hemoptoe, vascular complications.

b) Acute success of PVI after 1 freezing cycle

c) Duration of thaw phase (= time between end of freezing to automatic

deflation of the balloon) related to acute success of PVI

d) Procedure time, fluoroscopy time, amount of contrast used

e) LET development during and after ablation and relation of LET with balloon

temperatures measured by the console.

f) AF recurrence after 1 year follow up.

Study description

Background summary

Cryoballoon based therapy is an established therapy for the treatment of (paroxysmal) atrial fibrillation. However, with the rapid evolution in cryoablation technique and its increased effectiveness, the risk of complications increases. Therefore it is of utmost importance to define the optimal duration of cryoballoon ablation time.

Study objective

To assess the optimal ablation duration using the second generation cryoballoon for isolation of pulmonary veins in the treatment of atrial fibrillation.

Study design

The study is designed as a prospective multicentre randomized efficacy study.

Intervention

Patients will be randomized to 2 cycles of 1, 2 or 3 minutes of cryoballoon ablation after reaching the temperature "plateau phase*.

Study burden and risks

Since in this study a procedure which is common clinical practice will be performed, there is no extra risk or burden associated with the intervention.

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

* Paroxysmal atrial fibrillation eligible for PVI according to current international guidelines.
* Age < 75 years.
* Willing and able to sign informed consent.
* Willing to and capable of following the requested study procedures.

Exclusion criteria

* Age < 18 years.
* Pregnancy
* Life or follow-up expectancy < 12 months.
* Previous PVI.
* Contrast allergy.
* Creatin clearance level < 60.
* LVEF < 40%
* Abnormal left atrium anatomy defined as number of PV*s * 2 per side or LA diameter >50mm (measured in the parasternal long axis, as assessed with transthoracic echocardiography) or >40cc/m2. This will lead to exclusion after inclusion but before randomisation.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2014
Enrollment:	222
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	23-04-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-05-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	21-04-2016

Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	31-05-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-07-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	In clinicaltrials.gov, nog geen identificatienummer bekend
CCMO	NL47337.044.13