WATCHMAN Implantation during Hybrid Atrial Fibrillation Ablation

Published: 20-07-2015
Last updated: 19-04-2024

The primary objective of this study is to investigate the safety and feasibility of implanting a WATCHMAN Device in a hybrid setup for AF ablation.

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

Summary

ID

NL-OMON42540

Source
ToetsingOnline

Brief title
WINNING

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures
- Embolism and thrombosis

Synonym
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,Boston Scientific

Intervention

Keyword: Atrial fibrillation, Hybrid ablation, Safety, WATCHMAN

Outcome measures

Primary outcome

The primary safety endpoint for this study comprises major complications and includes:

* Acute death (< 7days after the procedure),

* Ischemic or hemorrhagic TIA or CVA (<7days after the procedure),

* Device embolization requiring retrieval,

* Device related complications requiring open surgery or major endovascular intervention,

* Any bleeding related to the device that necessitates a re-operation or PRBC transfusion * 2 Units within 24hours,

* Pericardial effusion requiring intervention (<3 months after the procedure),

* Femoral arteriovenous fistula.

The primary feasibility endpoint for this study is:

* Device success, defined as successful delivery and release of the WATCHMAN implant into the LAA, including successful recapture and retrieval if necessary, and residual peridevice flow is * 5 mm in width.

The primary efficacy endpoint comprises cardiovascular events during follow-up (>7days days):

* Cardiovascular or unexplained death,

* Embolic or hemorrhagic TIA or CVA,

* Systemic embolization.

Secondary outcome

The secondary endpoints for this study are:

* Prolonged procedure time,

* Prolonged radiation exposure time and dosage,

* (Serious) Adverse Device Events ((S)ADE),

* (S)AEs.

Study description

Background summary

Atrial fibrillation (AF) is the most common cardiac arrhythmia with a lifetime risk of developing AF of 1 in 4 people aged over 40. Stroke remains the most feared complication of AF with an increase in risk by 5-fold, and is the leading cause of morbidity and mortality. The left atrial appendage (LAA) is the origin for more than 90% of the emboli in non-valvular AF. The WATCHMAN* Left Atrial Closure Device (WATCHMAN Device, Boston Scientific) reduces the risk of stroke by closing off the LAA. During hybrid procedures for AF, LAA occlusion with epicardial devices is known to be difficult and not free of risks.It thus will be interesting to study the safety and feasibility of endocardial WATCHMAN Device implantation in a hybrid ablation approach.

Study objective

The primary objective of this study is to investigate the safety and feasibility of implanting a WATCHMAN Device in a hybrid setup for AF ablation.

Study design

The study is designed as a prospective, non-randomized, single center study. Ten consecutive patients will be included. The study will take place at the Maastricht University Medical Center, situated in Maastricht, the Netherlands. It is estimated that it will take 6-8 months to enroll the patients and a 6-months follow-up for all patients will be required. The estimated total study

duration will thus be 12 - 14 months.

Intervention

The intervention consists of the WATCHMAN Device implantation.

Study burden and risks

Patients who are included in this study, would also undergo LAA closure without participation in the study. The study only decides to use another as usual device, which has proven to be save, though in other settings. It is not expected that the WATCHMAN Device in the hybrid setting will be less save than in other settings and is even expected to be more save and more feasible than the method which is used at the moment.
When participating in this study, compared to a hybrid ablation without use of the WATCHMAN Device, patients will have one extra visit with TEE (at the same day) and one extra TEE performed on a day with a standard visit. These procedures however are related to the device implantation and are not solely for study purposes. Patient who would undergo a WATCHMAN Device implantation in a setting which is not hybrid, will have to undergo these same procedures.

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

The patient:
* Has documented paroxysmal or (long-standing) persistent non-valvular atrial fibrillation,
* Is eligible at least for short-term OAC therapy,
* Has no other conditions that would require long-term OAC therapy, suggested by current standard medical practice, and thus is eligible to stop OAC if the LAA is sealed,
* Has a calculated CHA2DS2-VASc score of 1 or more,
* Is 18 years of age or older, able and willing to provide written informed consent.

Exclusion criteria

* Current New York Heart Association Class IV Congestive Heart Failure,
* Current thrombocytopenia (< 100x10E9/L) or anemia (hemoglobin <6.2 mmol/L),
* Active infection or sepsis,
* Resting heart rate > 110 beats per minute,
* Cerebrovascular accident (CVA) or transient ischemic attack (TIA) within the last 30 days,
* Recent myocardial infarction (within 3 months),
* Transient case of AF (i.e., secondary to recent cardiac surgery (within 3 months)),
* Planned cardioversion 30 days post implant of the WATCHMAN Device,
* Implanted mechanical valve prosthesis,
* History of obliterated LAA,
* History of heart transplantation,
* Symptomatic carotid disease (i.e., carotid stenosis >50% associated with ipsilateral transient or visual ischemic attack evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral stroke within 6 months),
* Necessity to use long-term OAC,
* Contraindication for use of OAC or dual anti-platelet therapy,
* Contraindication for use of aspirin,
* Pregnancy or planned pregnancy during the course of the investigation,
* Life expectancy less than 2 years,
* Participation in any other clinical study involving an investigational drug or device.;Echocardiographic Exclusion Criteria (as assessed via transthoracic echocardiography (TTE) or TEE) for this study are:
* Left ventricular ejection fraction (LVEF) < 30%,
* Intracardiac thrombus as visualized by TEE within 2 days prior to implant,
* High risk patent foramen ovale,

* Current atrial septal defect and/or previous atrial septal repair or closure device,
* Significant mitral valve stenosis (i.e., MV 4. 5 cm2),
* Existing pericardial effusion of >3 mm,
* Complex atheroma with mobile plaque of the descending aorta and/or aortic arch,
* Cardiac tumor.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	WATCHMAN Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-07-2015
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL53510.068.15

Study results

Date completed:	19-06-2017
Actual enrolment:	10