Incremental value of systematic follow-up with CT after left atrial appendage occluder device implantation

Published: 07-08-2015
Last updated: 19-04-2024

Primary Objective: • Investigate if CT is a reliable modality to detect blood flow distal to the LAAO device validated by TEE.Secondary Objective(s): • Evaluate the reproducibility of position and blood flow measurements: inter and intra observer...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON42544

Source
ToetsingOnline

Brief title
follow-up with CT after left atrial appendage occluder device implantation

Condition

- Cardiac arrhythmias
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
Artrial appendix trombus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: implantation, left atrial appendage, Occluder

Outcome measures

Primary outcome

Investigate if CT is a reliable modality to detect blood flow distal to the LAAO device validated by TEE.

Secondary outcome

Evaluate the reproducibility of position and blood flow measurements: inter and intra observer variance, CT compared with TEE.

• Determine the optimal device position and size, based on pre-implantation anatomical CT data. Measurements of the LAA shape, ostium, depth and trabeculations in relation to the LAAO device landing position. When describing the ostium diameters specific attention can be placed on the oval shape as the ability of the device to change it from a circular to an oval shape is limited.

• Compare CT findings with clinical follow-up with specific interest for thromboembolic complications. Investigate if these can be related to suboptimal device position, trabeculations at the device landing zone, or contrast enhancement distal to the device.

• Size of the LAA distal to the device can be measured and compared to the LAA size as measured before implantation. Possibly allowing for volumetric

measurements of thrombus and to determine the ratio of contrast and thrombus

distal to the LAAO device.

Study description

Background summary

Atrial fibrillation can result in thrombus formation in the left atrial appendage, possibly resulting in a cerebrovascular accident (CVA). The antithrombotic treatment of atrial fibrillation includes anticoagulants in patients with a CHA2DS2-VASc score above one.1 Recently left atrial appendage occlusion (LAAO) devices have been introduced for patients who experience a CVA under anticoagulant treatment or with a contra-indication for anticoagulant medication. In the PROTECT-AF study 707 patients with non-valvular atrial fibrillation and at least one of the following risk factors: age >=75 years, hypertension, diabetes mellitus, heart failure, prior stroke, transient cerebral ischemic attack, or systemic thromboembolism were included. Included patients were randomized for LAAO device implantation or continuation of warfarin treatment. The LAAO group showed non-inferiority for thromboembolic complications. The majority of events in the LAAO implantation group were related to the implantation procedure.2 The 2012 ESC guidelines for atrium fibrillation provide a moderate recommendation (Class IIb level B) for LAAO device treatment in patients with contra-indications for anticoagulants.

In our institution approximately twenty patients are annually accepted for LAAO implantation. Following the protocol used in the PROTECT-AF study patients continue with warfarin (acenocoumarol) and aspirin for 45 days after implantation. After 45 days a trans esophageal echocardiography (TEE) is performed. When the peri-device flow is absent or smaller in diameter than 5mm the warfarin is discontinued and clopidogrel is started. After 6 months the clopidogrel is also discontinued and only aspirin is continued indefinitely. In case of a peri-device flow larger than 5mm the warfarin is continued at the 45 day interval. Periodically the peri-device flow will be measured again. If it becomes smaller than 5mm the warfarin can be stopped, and clopidogrel will be added following the protocol for peri-device flow below 5 mm.
Peri-device flow is defined as blood flow next to the LAAO, by using multiple angulations the maximal diameter is measured. Using CT contrast enhancement on the occluded (distal) side on the LAAO device will be measured. The contrast enhancement distal of the LAAO device will be compared with the peri-device flow measured with TEE. The ostium of the LAA is usually oval shaped. The LAAO occluder has a circular shape. This can result in incomplete coverage at the oval sides causing peri-device flow.
The PROTECT-AF study showed that in a substantial number of the patients (41%)

peri-device flow is present, and in 13% of the patients warfarin was continued at the 45 days interval.3
This study aims to prove CT is a reliable alternative for TEE to detect flow distal to the LAAO device. Currently one study has shown good results when comparing CT follow-up after LAAO device implantation with TEE, although this study included a limited number of patients and only patients implanted with an AMPLATZER type device.4 The type of device implanted is at the treating physician discretion, from current hospital records we expect the large majority of our cases to have been implanted a WATCHMAN type device.
If results of the CT scan post implantation are favorable a shift from TEE towards CT examinations might take place. This would save the patient an uncomfortable TEE procedure.

Study objective

Primary Objective:
• Investigate if CT is a reliable modality to detect blood flow distal to the LAAO device validated by TEE.

Secondary Objective(s):
• Evaluate the reproducibility of position and blood flow measurements: inter and intra observer variance, CT compared with TEE.

• Determine the optimal device position and size, based on pre-implantation anatomical CT data. Measurements of the LAA shape, ostium, depth and trabeculations in relation to the LAAO device landing position. When describing the ostium diameters specific attention can be placed on the oval shape as the ability of the device to change it from a circular to an oval shape is limited.

• Compare CT findings with clinical follow-up with specific interest for thromboembolic complications. Investigate if these can be related to suboptimal device position, trabeculations at the device landing zone, or contrast enhancement distal to the device.

• Size of the LAA distal to the device can be measured and compared to the LAA size as measured before implantation. Possibly allowing for volumetric measurements of thrombus and to determine the ratio of contrast and thrombus distal to the LAAO device.

Study design

The study is a single-center observational study.

The CT measurements will be compared with the standard of care TEE images. This study is performed in close collaboration with the cardiologists involved in the LAAO device implantation. We aim to include approximately 80% of the

patients accepted for the LAAO device implantation. We expect approximately thirty patients will be accepted annually for LAAO device implantation in our center. Patients will be informed about the study at the outpatient patient clinic. If the patient is accepted for LAAO device implantation the cardiologist will ask the patients to consider participation in the study and provide the study information documentation. If the patient is positive towards participation a follow-up consult with a research fellow (MD) will be made where the study design, patients risks, and population benefits are discussed in more detail.
The patients included will undergo a CT scan at the 45 days interval in addition to the TEE. The study will run until 41 patients are included. With an inclusion percentage of 80% we suspect to completed inclusion within 2 years.

Study burden and risks

Only patients who are accepted for LAAO device implantation will be included. Several radiation reduction techniques will be applied to reduce the radiation exposure for the study subjects. E.g. optimizing the selected scan mode prospective EKG triggered acquisition, and patient specific tube current and voltage modulation. The radiation dose from the complete CT scan will be approximately 3-5 mSv including both scans. The radiation dose is approximately double the annual radiation dosage from background radiation.5 The scan requires the injection of an iodine contrast agent. Patients known with contrast allergy will be excluded from the study. To minimize the risk of renal injury, patients with an impaired renal function (serum creatinine>120 *µmol/l or GFR<60 ml/min) will be excluded from the study.
Benefits:
There are no benefits for the individual subject.
Benefits to the population:
The study will help in creating protocols and measurement methods to follow-up patients after LAAO device implantation. Possible causing a shift from an inconvenient TEE to a CT scan.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 210
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 210
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patient accepted for LAAO device implantation.
• At least 18 years old
• Signed informed consent

Exclusion criteria

• Impaired renal function (serum creatinine > 120 umol/l or GFR<60 ml/min)
• Known allergy for iodine contrast agent
• Possible pregnancy
• Breast feeding

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-09-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	07-08-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL53138.078.15