Cardioblate Closure Device Closed Thorax Trial:An Evaluation of the Cardioblate® Closure* Device in Facilitating Occlusion of the Left Atrial Appendage in Closed Thorax Surgeries

Published: 11-01-2010
Last updated: 04-05-2024

This clinical study will evaluate the safety and performance of the Closure device to occlude the LAA during minimal invasive surgery. The objectives of the study are:• To evaluate the ability of the Cardioblate® Closure* device to occlude the LAA...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON33336

Source
ToetsingOnline

Brief title
Cardioblate Closure Device Closed Thorax Trial

Condition

- Cardiac arrhythmias

Synonym
cardiac rhythm disorders, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Cardiovascular Department SHD/RST
Source(s) of monetary or material Support: Het onderzoek wordt gefinancierd door industrie/bedrijf

Intervention

Keyword: Cardiac Surgery, Left atrial appendage, Occlusion, Performance

Outcome measures

Primary outcome

Primary efficacy endpoint

The primary efficacy endpoint will be effective occlusion of the LAA at

3-months follow-up using a computed tomography (CT) scan for those devices

placed successfully. A contrast enhanced CT-scan provides a better spatial

resolution and a higher sensitivity for blood communication than the classic

echocardiography.

The criteria for successful device placement and occlusion are the following:

Successful device placement

Placement of the Closure device is considered successful if the band is placed

<10 mm distal from the LA. The 10 mm distance is used to ensure that no large

opening remains present at the base of the LAA.

Successful occlusion of the LAA

Occlusion of the LAA is considered successful if no blood/contrast or a trace

of blood/contrast communication between the LA and LAA is present at the

3-month follow-up visit. Subjects who demonstrate mild, moderate, or severe

communication are not considered successes. The discrimination success / no

success is based on the relation between the level of blood communication and

the risk for thrombus formation. The detection of a trace of blood communication is considered a minor risk for the formation of thrombi as virtually no blood will flow from the LA to the LAA.

None: Zero detection of blood/contrast communication in all views into the LAA

Trace: < 2 mm in diameter detection of blood/contrast communication in all views into the LAA

Mild: 2-4 mm in diameter detection of blood/contrast communication in all views into the LAA

Moderate: > 4-6 mm in diameter detection of blood/contrast communication in all views into the LAA

Severe: > 6 mm in diameter detection of blood/contrast communication in all views into the LAA

Primary safety endpoint

The primary safety endpoint is the combined incidence of device-related adverse events that occur during device placement, or in the early post-operative period (30 days post-surgery or hospital discharge, whichever is longer). The device-related adverse events that could be expected to occur and are the primary safety endpoints are:

• LAA tears requiring surgical repair

• Bleeding requiring surgical intervention

• Unintentional tissue damage requiring surgical intervention

• Re-operation due to band displacement

• Incomplete occlusion of the LAA

Secondary outcome

Secondary endpoint

The secondary objective is to evaluate successful placement of the band. The secondary endpoint is the successful placement of the band, defined as 95% of the devices being properly placed onto the base of LAA (< 10 mm of residual stump proximal to the band) at the time of the procedure. Due to inter-individual anatomical differences a placement at the exact base of the LAA might not always be possible. To ensure that no significant residual stump remains, a maximum residue of 10 mm is determined as a successful band placement.

Study description

Background summary

The left atrial appendage (LAA) is a long, tubular, hooked structure which is usually crenellated and has a narrow junction with the venous component of the atrium. In patients with cardiac failure and especially atrial fibrilation (AF), there is an increase risk of the formation thrombi in the LAA. These thrombi pose a risk for strokes and other thromboembolic evenets. Patients at risk are typically maintained on anticoagulation therapy (warfarin) to reduce the risk of stroke. Warfarin studies have shown some risks to include fatal or nonfatal hemorrhage from tissue or organ, bleeding, and necrosis of the skin and other tissues.The concept of removing the LAA in order to prevent stroke dates back to the earliest mitral valvotomy procedure for rheumatic mitral stenosis in the 1930*s. The LAA is then occluded during a concommitant surgery for an other indication. Usually sutures or stappler device are used. These method have proven their effectivity but are difficult to perform dirng minmal invastive surgery. Medtronic has developed the Cardioblate closure device in order to occlude the LAA in a safe and easy manner also during minimal invasive surgery.

Study objective

This clinical study will evaluate the safety and performance of the Closure device to occlude the LAA during minimal invasive surgery.
The objectives of the study are:
• To evaluate the ability of the Cardioblate® Closure* device to occlude the LAA during Closed Thorax surgical procedures at 3 months post-surgery as measured by a CT scan.
• To evaluate the composite incidence rate of device-related adverse events during device placement and within 30 days post-surgery or hospital discharge, whichever is longer;
• To evaluate successful placement of the band where successful placement is defined as 95% of the devices being properly placed onto the base of LAA (<10 mm of residual stump proximal to the band) at the time of the procedure;

Study design

Prospective, non-randomised, multi-center post market release study.

Intervention

In the participating patients, the left atrial appendage (LAA) will be occluded using the Cardioblate® Closure* Device, during minimally invasive cardiac surgery. The occlusion of the LAA will be concomitant to an other cardiac procedure (ea heart valve replacement, surgical ablation, coronary artery bypass grafting). In order to evaluate successful band placement and occlusion of the LAA, a trans-esophagus echocardiogram will be performed during surgery.
After the surgical procedure the patient is scheduled for 3 follow-up visits.
During the follow-up visits the following data will be collected:
- Adverse events
- NYHA classification
- CHADS score
- Anticoagulation medication status
At the 3 month follow-up visit, a CT scan will be performed to asses the blood communication between the LA and the LAA.

Study burden and risks

Study subjects must be informed of all known potential side effects and complications associated with study treatment and evaluations prior to enrollment in the study. The benefits of the conduct of this study outweigh the potential risks for the participants.
Potential Risks
Risks associated with the Closure device are not yet known. Potential risks associated with occlusion of the LAA are, but not limited to:
• LAA tear requiring surgical repair
• Bleeding requiring surgical re-operation intervention
• Unintentional tissue damage requiring surgical intervention

• Re-operation due to band displacement
• Incomplete occlusion of the LAA
Standard risks associated with any cardiac surgery being performed in conjunction with LAA occlusion should be discussed with the subject in detail by the Investigator. Identified risks associated with cardiac surgery are, but not limited to:
• Stroke
• Heart attack
• Graft failure
• Loss of life
• Serious bleeding
• Heart or lung problems
• Kidney failure
• Allergic reaction to medication
• Nerve or organ damage
Risks associated with the TEE
• Tissue damage of the esophagus and the troth
• Allergic reaction to lubricant
The CT scan poses almost no risk to subjects. Potential risks associated with a CT scan are:
• Risks associated with heavy sedation, if used
• Allergic reaction to contrast
• Risk of cancer from radiation
The risks associated with the CT scan are very low and will not provide an additional health risk.
Based on a review send to the TUV (Clinical Evidence Report AF007/D02987) of comparable devices, a list of device-related Adverse Events including their incidence rates is provided in table 3.
The treatment in this study will not interfere with other treatments or medical interventions as subjects with the risk of such possible interactions are excluded by the exclusion criteria.

Incidence rates of device related AE*s of comparable products
Adverse Event Incidence rate %
LAA tears 4.29
Bleeding 0.23
Tissue damage needing surgical repair 0.0

Risk minimization
Subjects are required to have a need for cardiac surgery other than closure of the LAA. The majority of risk for these subjects will be in undergoing closed thorax cardiac surgery for the concomitant procedure. The additional time required for Closure band placement and the potential adverse events related to this procedure are minimal in comparison to the concomitant procedure. These risks will be minimized by providing adequate training to the cardiac surgeon performing the procedure.

Potential benefits associated with the procedure/study
Participation in this study is voluntary. Although this study is not intended to demonstrate a reduction in thromboemboli for subjects with AF, it has been studied that occlusion or removal of the LAA may decrease thrombus formation in the LA in some subjects. Subjects may or may not benefit from this procedure.

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

Subjects who meet the following criteria should be considered for the study:
1) >18 and < 80 years of age
2) Concomitant indication for closed thorax cardiac surgery for one or more of the following:
a. Mitral valve repair or replacement
b. Aortic valve repair or replacement

c. Tricuspid valve repair or replacement
d. CABG for subjects >60 years of age
e. CABG for subjects <60 years of age with a history of AF
f. Surgical ablation or Maze procedure
3) The subject is willing and able to provide written informed consent and comply with study requirements

Exclusion criteria

Subjects who meet any of the following criteria should not be considered for the study:
1) Thrombus in LAA and/or LA
2) Prior LAA isolation attempt(s)
3) Patient is contraindicated for an intra-operative transesophageal echocardiogram (TEE)
4) Unable to take an anticoagulant during the study follow-up period
5) Subject is undergoing an emergency cardiac procedure
6) Life expectancy of less than 12 months
7) Pregnancy or desire to be pregnant within 12 months of the study procedure

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-01-2010

Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL29007.075.09