Prospective randomized multi-center controlled clinical investigation comparing PFO outcomes of the Occlutech Flex II PFO Occluder to standard of care PFO occlusion.

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The purpose of this clinical study is the assessment of the safety and effectiveness of the Flex II PFO Occluder in the treatment of subjects 18 years of age or older who have had a cryptogenic stroke due to a presumed paradoxical embolism as...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON53694

Source
ToetsingOnline

Brief title
Occluflex

Condition

- Central nervous system vascular disorders
- Embolism and thrombosis

Synonym
Patent Foramen Ovale, Unclosed atrial septa

Research involving
Human

Sponsors and support

Primary sponsor: Occlutech US LLC
Source(s) of monetary or material Support: industry

Intervention

Keyword: Atrial septa, Patent foramen ovale, PFO closure

Outcome measures

Primary outcome

Effective Closure rates of the PFO, where effective PFO closure is defined as <=

25 bubbles demonstrated by TTE and bubble study at 12-month follow-up.

Secondary outcome

Non-fatal recurrent stroke through 12-month follow-up, which is defined as:

1. An acute focal neurological deficit presumed due to focal ischemia and

either:

2. persisting over 24 hours, or persisting for less than 24 hours but

associated with a new cerebral infarct documented with MRI or CT

Study description

Background summary

The rationale for conducting this investigation is that the safety and effectiveness of PFO Closure to reduce the risk of recurrent ischemic stroke has been established in two prospective randomized controlled clinical investigations when compared to medical therapy alone. The Flex II PFO Occluder is similar in design to the approved occluders, therefore, a randomized study comparing the Flex II PFO Occluder investigational device to approved PFO devices is appropriate.

Study objective

The purpose of this clinical study is the assessment of the safety and

effectiveness of the Flex II PFO Occluder in the treatment of subjects 18 years of age or older who have had a cryptogenic stroke due to a presumed paradoxical embolism as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke, and the presence of a PFO determined by echocardiography.

The objective of this study is to investigate whether percutaneous PFO closure with the Occlutech Flex II PFO Occluder is non-inferior to the AMPLATZER* PFO Occluder and Gore® Cardioform Septal Occluder in closure of the PFO, prevention of recurrent embolic stroke, and device/procedure related SAEs

Study design

The OCCLUFLEX PFO Study is a randomized prospective, multi-center global study comparing the clinical outcomes of the Flex II PFO Occluder to the standard of care PFO Occlusion devices, which includes the Amplatzer PFO Occluder and the Gore Cardioform PFO Occluder. Randomization will be 1:1 and will occur within 5 workingdays of the implant procedure.
The total duration of the study is expected to be 5 years (60 months).
The clinical study will be conducted in approximately 60 centers in the US, Canada, and Europe.
Up to 450 subjects will be enrolled in this study.
Subjects will be followed up for 12 months for endpoint analysis and then yearly up to 5 years post implant. Upon PMA approval subjects will be rolled into a post approval study up to 5 years post implant.

Intervention

The following investigational devices will be used for the OCCLUFLEX PFO Study:
• Flex II PFO Occluder
• Occlutech Pistol Pusher delivery system
The following market released devices and delivery systems will be used for the study:
• Amplatzer PFO Occluder
• Amplatzer Torqvue Delivery System
• Gore Cardioform PFO Occluder and Delivery System
• Cook Sheath
• Occlutech Delivery Set

Randomization will be 1:1 and will occur within 5 workdays of the implant procedure.

Study burden and risks

Though the PFO procedure has risks associated with the study device and the comparator devices, there are no extra risk that are directly related to the

study as all devices (study and comparators) are all approved for use on the market and they will be used within the intended purpose.
Risk / adverse events associated with the study device and comparators are listed in section 5 of the protocol.

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 with a PFO and cryptogenic stroke:
• PFO defined as visualization of microbubbles (during TEE) in the left atrium within three cardiac cycles of right atrial opacification at rest and/or with Valsalva.
• Cryptogenic stroke defined as a stroke of unknown cause.
• Stroke defined as an acute focal neurological deficit, presumed to be due to

focal ischemia, and either:
o Symptoms persisting >=24 hours, or
o Symptoms persisting <24 hours with MR or CT findings of a new, neuroanatomically relevant, cerebral infarct.

Exclusion criteria

General:
• Age <18 years
• MI or unstable angina within 6 months
• Mitral or aortic valve stenosis or severe regurgitation
• LVEF <35%
• Uncontrolled hypertension or diabetes mellitus despite medications
• Subjects contraindicated for aspirin or clopidogrel
• Subjects not able to discontinue anticoagulation
• Qualifying stroke with Modified Rankin score >3
• Anatomy in which the device would interfere with intracardiac or vascular structures
• Life expectancy < 2 years
Exclusion for patients with known causes of ischemic stroke:
• Atrial fibrillation/atrial flutter (chronic or intermittent)
• LV aneurysm, intracardiac thrombus, or tumor
• Mitral or aortic valve vegetation or prosthesis
• Aortic arch plaques protruding >4 mm into the lumen
• Atherosclerosis or arteriopathy of intra- or extracranial vessels with >50% diameter stenosis in the artery supplying the infarcted territory
• Another cause of right-to-left shunting (e.g., an ASD or a fenestrated atrial septum)
• Presence of an arterial hypercoagulable state:
o Lupus anticoagulant,
o anticardiolipin Abs,
o hyperhomocysteinemia,
o Cancer-related hypercoagulability.
• Lacunar infarct probably due to intrinsic small vessel as the qualifying event, defined as an ischemic stroke in the distribution of a single, small deep penetrating vessel in a patient with any of the following:
o A history of hypertension (except in the first week post stroke)
o A history of diabetes mellitus
o Age >=50 years
o MRI or CT with leukoaraiosis greater than symmetric, well-defined periventricular caps, or bands (European Task Force on Age-Related White Matter Changes rating scale score >0)
• Arterial dissection as the qualifying event

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-08-2023
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Figulla® Flex II PFO Occluder
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-03-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-06-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	28-11-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-07-2024
Application type:	Amendment
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
Other	05069558
CCMO	NL81852.078.22