WATCHMAN FLX versus NOAC for EMbolic ProtectION in the management of patients with Non-Valvular Atrial Fibrillation (CHAMPION-AF) S2437

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The primary objective of this study is to determine if left atrial appendage closure with the WATCHMAN FLX device is a reasonablealternative to non-vitamin K oral anticoagulants (NOACs) in patients with non-valvular atrial fibrillation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54473

Source
ToetsingOnline

Brief title
Champion-AF (2437)

Condition

- Other condition
- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Cardiac arrhythmias

Synonym
non-valvular atrial fibrillation

Health condition

non-valvular atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Clinical Research Organisations
Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: left atrial appendage, non-valvular atrial fibrillation, reduce, thromboembolism

Outcome measures

Primary outcome

1. WATCHMAN FLX is non-inferior for the occurrence of stroke (including ischemic and/or hemorrhagic), cardiovascular (CV) death (including hemorrhagic and/or unexplained death), and systemic embolism at 36-months. This endpoint is defined as the Kaplan Meier estimate of time to first occurrence of stroke (including ischemic and/or hemorrhagic), all CV death, or systemic embolism at 36 months.

2. WATCHMAN FLX is superior for non-procedural bleeding (ISTH major bleeding and clinically relevant non-major bleeding) at 36-months. This endpoint is defined as the Kaplan Meier estimate of time to first occurrence of non-procedural ISTH major bleeding or clinically relevant nonmajor bleeding through 36- months.

Secondary outcome

The occurrence of ISTH major bleeding at 36-months. First test NI at 36-months, if passed then test for superiority at 60-months.

The occurrence of cardiovascular (CV) death, disabling stroke, systemic

embolism (SE), and non-procedural bleeding (ISTH major bleeding and

clinically relevant non-major bleeding) at 36-months. First test NI at

36-months, if passed then test for superiority at 60-months.

Study description

Background summary

As the risk of stroke increases with age and the disability and tolerance concerns with available drug therapies persist, the need for permanent protection against thromboembolism in AF patients remains unmet. The sponsor developed the WATCHMANTM and WATCHMAN FLXTM Left Atrial Appendage Closure (LAAC) Devices, permanent implantable devices designed to seal off the left atrial appendage (i.e., the location where the

Study objective

The primary objective of this study is to determine if left atrial appendage closure with the WATCHMAN FLX device is a reasonable alternative to non-vitamin K oral anticoagulants (NOACs) in patients with non-valvular atrial fibrillation.

Study design

This study is a prospective, randomized, multi-center global investigation to determine if left atrial appendage closure with the WATCHMAN FLX Device is a reasonable alternative to NOACs in patients with non-valvular atrial fibrillation.

Intervention

Patients will undergo a standard treatment

Study burden and risks

Both treatments are used in standard of care

Contacts

Public
Clinical Research Organisations

Boston Scientific International SA Parc Val Saint-Quentin, Bâtiment H, 2 Rue René Caudron
Voisins le Bretonneux, 78960
FR
Scientific
Clinical Research Organisations

Boston Scientific International SA Parc Val Saint-Quentin, Bâtiment H, 2 Rue René Caudron
Voisins le Bretonneux, 78960
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. The subject is of legal age to participate in the study per the laws of their respective geography
2. The subject has documented non-valvular atrial fibrillation (i.e., atrial fibrillation in the absence of moderate or greater mitral stenosis or a mechanical heart valve)
3. The subject has a calculated CHA2DS2-VASc score of 2 or greater for men and 3 or greater for women
4. The subject is deemed to be suitable for the protocol defined pharmacologic regimens in both the test and control arms

Exclusion criteria

1.The subject requires long-term anticoagulation therapy for reasons other than AF-related stroke risk reduction, for example due to an underlying hypercoagulable state (i.e., even if the device is implanted, the subjects would not be eligible to discontinue OAC due to other medical conditions requiring chronic OAC therapy)
3. The subject is contraindicated or allergic to oral anticoagulation medication and/or aspirin
4. The subject is indicated for chronic P2Y12 platelet inhibitor therapy
5. The subject had or is planning to have any cardiac or non-cardiac intervention or surgical procedure within 30 days prior to or 60 days after implant (including, but not limited to: cardioversion, percutaneous coronary intervention (PCI), cardiac ablation, cataract surgery, etc.)
6. The subject had a prior stroke (of any cause, whether ischemic or hemorrhagic) or transient ischemic attack (TIA) within the 30 days prior to enrollment
7. The subject had a prior major bleeding event per ISTH definition within the 30 days prior to randomization. Lack of resolution of related clinical sequelae or planned and pending interventions to resolve bleeding/bleeding source, are a further exclusion regardless of timing of the bleeding event
8. The subject has an active bleed
9. The subject is of childbearing potential and is, or plans to become, pregnant during the time of the study

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):	03-12-2021
Enrollment:	3
Type:	Actual

Medical products/devices used

Generic name:	Commercially available Watchman FLX
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-02-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-05-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL75294.100.20
Other	to be notified