Rotterdam Edoxaban Leaflet Evaluation in Patients after Transcatheter Aortic Valve Implantation

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To investigate whether treatment with edoxaban leads to a decrease in incidence of leaflet thickening and is clinical efficient and safe.

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

Summary

ID

NL-OMON52528

Source
ToetsingOnline

Brief title
REDOX TAVI

Condition

- Cardiac valve disorders

Synonym
Aortic stenosis, Narrowing of the aortic valve

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Daiichi Sankyo Europe GmbH

Intervention

Keyword: Aortic Stenosis, Edoxaban, Leaflet Thickening, TAVI

Outcome measures

Primary outcome

To investigate whether edoxaban affects the incidence of aortic valve leaflet thickening after TAVI as assessed by cardiac 4DCT-scan after 3 months treatment.

Secondary outcome

To investigate the occurrence of reduced THV leaflet motion by MSCT at 3 months of follow up.

To investigate whether treatment with edoxaban affects transprosthetic gradients (i.e. change in transprosthetic gradient, effective orifice area and doppler velocity index between TTE at discharge and at 1 year) after TAVI.

The occurrence and increase of aortic regurgitation as determined by transthoracic echocardiography pre-discharge and at 12 months.

To investigate the safety of edoxaban treatment in patients undergoing TAVI -with no formal OAC indication- on net adverse clinical outcomes after 1 month, 3 months and one year; i.e.: the composite of all-cause death, myocardial infarction (MI), ischemic stroke, systemic thromboembolism, valve thrombosis and major bleeding (International Society on Thrombosis and Hemostasis [ISTH] definition) and every endpoint separately including any neurological event

(minor/disabling stroke and TIA)

To investigate the effect of edoxaban treatment in patients undergoing TAVI

-with no formal OAC indication- on major bleeding at 1 month, 3 months and one

year.

Study description

Background summary

Thromboembolic- and bleeding events can occur after TAVI and can have great consequences. There is currently no evidence-based guideline on prevention of thromboembolic events after TAVI and the current standard of care with DAPT 3-6 months is based on expert opinion. Recently multislice computed tomography (MSCT) studies identified bioprosthesis leaflet thickening and impaired leaflet motion after TAVI.
The goal of this study is to investigate whether in TAVI patients, treatment with edoxaban leads to a reduction in leaflet thickening incidence after 3 months and whether it is safe and clinically efficient.

Study objective

To investigate whether treatment with edoxaban leads to a decrease in incidence of leaflet thickening and is clinical efficient and safe.

Study design

A single-center, investigator-initiated, sponsored, open-label, observational study.

Intervention

Patients will be treated with edoxaban for a period of 3 months following TAVI. Afterwards they will switch to standard acetylsalicylic acid.

Study burden and risks

Thusfar edoxaban has proven to be safe and non-inferior to treatment with warfarin in several indications. The role of anticoagulant agents in TAVI still

has to be unravelled. Subjects participating in this trial are possibly at higher risk for bleeding complications than patients being treated with dual antiplatelet therapy after TAVI.

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

Patients completed successful elective TAVI for severe aortic valve stenosis with any commercially-available transcatheter heart valve (THV).
-Correct positioning of a single prosthetic heart valve into the proper anatomical location
-Device success, defined by Mean aortic valve gradient < 20 mmHg; Peak transvalvular velocity <3.0 m/s; Aortic valve regurgitation of 2 or less, No periprocedural complications

- No overt stroke
- No uncontrolled bleeding
- No major vascular complication defined by the VARC-3 consensus, No formal indication for oral anticoagulation
- No cardiac structural complication defined by the VARC-3 consensus
- Prevention of thromboembolic complications in patients with atrial fibrillation
- Prevention for recurrent venous thromboembolism
- Prevention for recurrent pulmonary embolism

Exclusion criteria

History of life-threatening or major bleeding event >= BARC 3b definitions within the last year
Other conditions with a high risk of bleeding
- Active peptic ulcer or upper gastrointestinal bleeding within last 3 months prior to enrolment
- Malignancy with high risk of bleeding
- Recent unresolved brain of spinal injury
- Spinal or ophthalmic surgery within last 3 months prior to enrolment
- Intracranial haemorrhage
- Esophagal varices
- Atriovenous malformations with high risk of bleeding
- Vascular aneurysms
- Major intraspinal or intracerebral vascular abnormalities
Hypersensitivity or contraindications to edoxaban
Requirement for dual-antiplatelet therapy (DAPT) within 1 month prior to enrolment
Concomitant percutaneous coronary intervention (PCI) during the TAVI procedure, requiring DAPT after the procedure.
Renal impairment defined as by dialysis-dependency or GFR < 30 mL/min at time of enrollment
Active bleeding or bleeding diasthesis including thrombocytopenia (platelet count < 50.000 cells/UL), thrombobasthenia, haemophilia or von Willebrand disease
Patients unable to adhere to or complete the investigational protocol for any reason including but not limited to geographical residence, psychiatric condtition or life-threatening disease
Pregnant or breast-feeding subjects
Current participation in clinical trials that potentially interfere with the current study

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2019
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lixiana
Generic name:	Edoxaban
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-04-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	04-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	24-02-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2022
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
EudraCT	EUCTR2019-001425-26-NL
CCMO	NL69611.078.19