A comparison between rivaroxaban-based strategy and antiplatelet-based strategy following successful TAVR for prevention of leaflet thickening and reduced leaflet motion as evaluated by four-dimensional, volume-rendered computed tomography (4DCT) in a population of patients coming from the GALILEO randomized trial

Published: 01-06-2017
Last updated: 13-04-2024

Evaluate whether a rivaroxaban-based strategy, following successful TAVR, compared to an antiplatelet-based strategy, is superior in reducing subclinical valve leaflet thickening and motion abnormalities - as evaluated by 4DCT imaging at three...

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

Summary

ID

NL-OMON45677

Source
ToetsingOnline

Brief title
GALILEO-4D

Condition

- Cardiac valve disorders

Synonym
new valve leaflet, valve leaflet thickening/movement

Research involving
Human

Sponsors and support

Primary sponsor: European Cardiovascular Research Institute (ECRI)
Source(s) of monetary or material Support: Bayer,only via grant

Intervention

Keyword: 4DC, antiplatelet-based, rivaroxaban-based, TAVR

Outcome measures

Primary outcome

The rate of patients with at least one prosthetic leaflet with > 50% motion

reduction as assessed by cardiac 4DCT-scan (total N = 300).

Secondary outcome

- The rate of prosthetic leaflets with > 50% motion reduction as assessed by

cardiac 4DCT-scan (based on a total of 900 observations in N = 300 patients).

- The rate of patients with at least one prosthetic leaflet with thickening as

assessed by cardiac 4DCT-scan (total N = 300).

- The rate of prosthetic leaflets with thickening as assessed by cardiac

4DCT-scan (based on a total of 900 observations in N = 300 patients).

- Aortic transvalvular mean pressure gradient and effective orifice area (cm2)

as determined by transthoracic echocardiography.

- Functional NYHA class.

- Death, first thromboembolic event (DTE), and safety endpoints (see GALILEO trial) will be assessed in the main GALILEO study and analyzed in the GALILEO-4D substudy with regards to occurence of the leaflet abnormalities - as exploratory analysis.

Study description

Background summary

An optimal therapy for TAVR patients is not known and only based on consensus, there is an unmet need to identify the best medical treatment in patients undergoing TAVR.

Study objective

Evaluate whether a rivaroxaban-based strategy, following successful TAVR, compared to an antiplatelet-based strategy, is superior in reducing subclinical valve leaflet thickening and motion abnormalities - as evaluated by 4DCT imaging at three months following TAVR.

Study design

Within the GALILEO main study, patients will be randomized 1:1 to an antiplatelet-based strategy vs. rivaroxaban-based strategy. At selected sites participating subjects will be offered to additionally take part in the GALILEO-4D sub study. For the GALILEO-4D sub study the following additional assessments will be performed at 90 days (+/- 15) after randomization in the main study: 4DCT scan, tECG and functional NYHA classification.

Intervention

during visit main Galileo studie: 4DCT, tECG and NYHA functional class

Study burden and risks

Subjects will have an additional radiation burden of 5-15 mSv for the GALILEO-4D sub study. This corresponds to 2-6 times the background radiation in the Netherlands (ca. 2.5 mSv annually).

Contacts

Public
European Cardiovascular Research Institute (ECRI)

Westblaak 92
Rotterdam 3012 KM
NL
Scientific
European Cardiovascular Research Institute (ECRI)

Westblaak 92
Rotterdam 3012 KM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patient included in the randomized GALILEO trial
2. Written informed consent

Exclusion criteria

1. Severe renal insufficiency (eGFR < 30 ml/min/1.73 m2) or on dialysis, or post-TAVR unresolved acute kidney injury with renal dysfunction >= stage 2
2. Iodinate contrast media allergy or other conditions that prohibit CT imaging (i.e. multiple myeloma, etc.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2017
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02833948
CCMO	NL59279.018.17