PROSE: Prospective Randomized On-X / St. Jude Medical Evaluation

Published: 14-07-2009
Last updated: 06-05-2024

To investigate whether the incidence of major thromboembolic complications is reduced with On-X compared to St. Jude medical.

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

Summary

ID

NL-OMON39125

Source
ToetsingOnline

Brief title
PROSE study

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
Bloodclot complications, incidence of obstruction due to bloodclot.

Research involving
Human

Sponsors and support

Primary sponsor: On-X Life Technologies, Inc
Source(s) of monetary or material Support: On-X Life Technologies

Intervention

Keyword: AVR, Mechanical Heart Valve, MVR

Outcome measures

Primary outcome

Incidence of major thromboembolic events during 5 year FU

Secondary outcome

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Study description

Background summary

To investigate the incidence of longterm major thromboembolic complications after hartvalve repalcement with a mechanical heart valve.

Study objective

To investigate whether the incidence of major thromboembolic complications is reduced with On-X compared to St. Jude medical.

Study design

A Multi-centre randomized trial to sequentially enroll 250 eligible patients in each group (500 total) from 10-15 participating centres in North America and Europe. It is estimated that each centre will be able to randomize 30-40 patients. The final analysis will begin approximately one year after the final patient has been enrolled, resulting in study comparison.

Intervention

Haert Valve replacement of the Mitral valve or Aortic valve with a mechanical heart valve prothesis.

Study burden and risks

Standard risks for open heart surgery and heart valve replacement with a

mechanical heart valve.

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

1. Isolated mitral - or isolated aortic valve replacement (eligible for coronary artery bypass and / or concomitant repair of mitral of tricuspid valves)
2. Candidate for receipt of mechanical heart valve

Exclusion criteria

Patient is not a candidate to receive a mechanical heart valve

Double valve replacement
Patient requires tricuspid valve replacement
Enrollment in another investigative trial / study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2009
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	14-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	30-10-2013
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	GOV NCT 00639782
CCMO	NL27949.078.09