

Long-Term Follow-Up of the Freestyle Stentless Bioprosthesis

Published: 25-11-2014

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To evaluate long-term outcome of the Freestyle bioprosthesis in the aortic position

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

Summary

ID

NL-OMON40663

Source

ToetsingOnline

Brief title

Freestyle Study

Condition

- Cardiac valve disorders

Synonym

aortic root pathology, Aortic valve pathology

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Medtronic B.V.,Medtronic;Inc;Minneapolis;MN;Verenigde Staten

Intervention

Keyword: Aortic Root, Freestyle, stenless bioprosthesis

Outcome measures

Primary outcome

Structural valve deterioration

Secondary outcome

Valve-related mortality

Valve related events (nonstructural valve dysfunction, valve thrombosis, thromboembolism, hemorrhage, valve endocarditis)

Hemodynamic performance (effective orifice area, peak transvalvular gradient, LV mass reduction)

Quality of life (physical health, mental health)

Study description

Background summary

Little information exists on long-term durability of the Freestyle bioprosthesis as it requires sufficient follow-up. At Leiden University Medical Center, the Freestyle bioprosthesis is used since June 1993.

Study objective

To evaluate long-term outcome of the Freestyle bioprosthesis in the aortic position

Study design

Investigator initiated single-center observational study

Study burden and risks

Minimal burden and no risks are expected.

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

Implantation of the Freestyle bioprosthesis in the LUMC

Exclusion criteria

Explantation of Freestyle bioprosthesis

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 24-12-2014

Enrollment: 250

Type: Actual

Ethics review

Approved WMO

Date: 25-11-2014

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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

CCMO

ID

NL49058.058.14