Hancock II Ultra Porcine Bioprosthesis Hemodynamic Study

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

Summary

ID

NL-OMON38091

Source
ToetsingOnline

Brief title
Hancock II Ultra

Condition

- Cardiac valve disorders

Synonym
aortic valve disease

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: de sponsor van het onderzoek;Medtronic.

Intervention

Keyword: Cardiovascular Diseases, Heart Valve Diseases

Outcome measures

Primary outcome

The primary objective of the study is the hemodynamic performance of the bioprosthesis at 6 and 12 months after surgery. This will be measured by comparing the mean aortic valve gradients pre-and post-surgery.

Secondary outcome

The secondary endpoint of the study is the incidence of patient prosthesis mismatch (PPM). During implant, the valve size of the patient's annulus will be measured using universal sizer and Hancock II Ultra sizer, and these measurements will be compare to valve sizes ultimately used for implant. In this way we can find out which valve size is most suitable for a certain native annulus diameter.

Study description

Background summary

Since the first implant in September 1982, the Medtronic Hancock® II has provided more than 20 years of excellent hemodynamic performance and durability. Design improvements over the past generations include: low profile, flexible stent, Supra-XTM supra-annular placement, T6 anticalcification tissue treatment, modified fixation process, CINCH® advanced implant system and ULTRA TM minimized sewing ring. Valve sizing is a critical consideration in obtaining optimal hemodynamic performance. This is particular true in small aortic roots. A critical issue is the size of the prosthesis in relation to the patient's annulus.

Study objective

The objective of this clinical study is to evaluate, at six and twelve months, the hemodynamic performance of the Hancock® Ultra* bioprosthesis in the aortic position, to analyze the incidence of patient prosthesis mismatch and the correlation of gradients.

Study design

Non-Interventional non-randomized multi-center prospective post-market release clinical study.

Study burden and risks

The Hancock® Ultra * bioprosthesis used in this study are CE-marked and thus available on the market. There are no additional risks or benefits for the patient to participate, other than the normally associated risks of cardiac surgery and the use of a heart lung machine. No additional or particular diagnostic or other procedures, above normal standard of care, will be performed on study patients as a result of participation in the study. Data will be collected without any burden to the patient.

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 who require aortic valve replacement with or without coronary artery bypass grafting or
surgical treatment of atrial fibrillation or mitral valve repair.
- Patients who are able to provide informed consent.

Exclusion criteria

- Concomitant procedures other than coronary artery bypass grafting, surgical treatment of atrial
fibrillation or mitral valve repair.
- Patients indicated for receiving a mechanical prosthesis.
- Patients who will have a replacement of existing valve prosthesis.
- Patients refusing or not able to provide informed consent.
- Patients requiring emergency surgery.
- Patients unable to participate in follow-up

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-11-2011

Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT01213615
CCMO	NL35653.058.11