Corcym Mitral, Aortic aNd Tricuspid post-maRket Study in a reAl-world setting

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Monitor ongoing safety and performance of the CORCYM heart valve devices and accessories for aortic, mitral and tricuspid valvular diseases in a real-world setting.

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

Summary

ID

NL-OMON52268

Source
ToetsingOnline

Brief title
MANTRA study LNH800

Condition

- Cardiac valve disorders

Synonym
heart valve disease, heart valve replacement

Research involving
Human

Sponsors and support

Primary sponsor: Corcym S.r.l
Source(s) of monetary or material Support: Corcym S.r. l

Intervention

Keyword: aortic, mitral and tricuspid valvular diseases, observational, post-market, safety

and performance

Outcome measures

Primary outcome

Safety and performance assessments during the study, up to 10 years after implantation.

Endpoints are defined in detail in the sub-study specific protocols.

Secondary outcome

Statistical strategy, calculation sample handling, data analysis, and reporting methods are described in each sub-study protocol by study-specific design, objective, and planned endpoints of the study.

Study description

Background summary

The sponsor of this clinical trial has a full portfolio, including mechanical and biological, heart valves for mitral and/or aortic valve replacement and bands/rings for mitral or tricuspid valve repair, which provide the surgeon with a variety of treatment options that can be chosen based on the anatomy and pathophysiology of the individual patient. All products have received CE marking or other local approval and are commercially available.

Study objective

Monitor ongoing safety and performance of the CORCYM heart valve devices and accessories for aortic, mitral and tricuspid valvular diseases in a real-world setting.

Study design

Patients may participate in this clinical trial if one (or more) of the heart valves (aortic, mitral, or tricuspid) is not working properly.
The physician will review whether heart valve surgery is required. This surgery is performed to repair the existing valve to restore valve function or to replace a damaged valve with a biological or mechanical prosthesis. Heart valve

replacement is usually considered an appropriate option only when repair is not possible. As the clinical trial collects information about the disease and standard treatment, data are collected on health status before and after treatment.

Umbrella Study Concept = adaptive study design:
One trial infrastructure (=Master)
Evaluation of multiple investigational therapies or therapeutics areas
Master protocol to contain endpoints applicable across the treatment groups
Several substudies can be added as needed

Study burden and risks

The participation in this study will last approximately 5 and up to 10 years for the participants. During this period, the physician-investigator will collect information related to the patient's vital signs, the evolution of the clinical condition, any blood thinning medication, and the results of the prescribed tests, in accordance with the standard of care:

-Blood test
-ECG results (An electrocardiogram or ECG is a recording of the electrical activity of the heart. An ECG is a simple, non-invasive procedure. Electrodes are placed on the skin of the chest and connected in a specific order to a machine that, when turned on, measures electrical activity across the heart)
-Echocardiography (A diagnostic test that uses high-frequency sound waves to create images of the heart chambers, valves and surrounding structures)
-Questionnaires quality of Life

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

- Signed and dated approved Informed Consent
- Subject is willing and able to comply with the follow up schedule of the protocol
- Eligible for treatment with Corcym aortic, mitral/tricuspid products as outlined in the applicable IFUs

Exclusion criteria

-Subject is already participating to another clinical investigation that could confound the results of this clinical investigation
-Subject has a life expectancy <= 12 months
-Subject has contraindications to the use of Corcym aortic, mitral and/or tricuspid devices as outlined in the applicable Instructions For Use (IFU)

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2022
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NCT05002543
CCMO	NL78973.042.21