Expanded Clinical Study of Tendyne Mitral Valve System

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Primary Safety Objective : To evaluate one month procedural and device safety of the Tendyne Bioprosthetic Mitral Valve System.Primary Safety Endpoint : Device success and freedom from the following device- or procedure-related serious adverse...

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

Summary

ID

NL-OMON50124

Source
ToetsingOnline

Brief title
Tendyne Study CS-03

Condition

- Cardiac valve disorders

Synonym
severe mitral regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: Tendyne Holdings, Inc
Source(s) of monetary or material Support: Manufacturer of the study device

Intervention

Keyword: Effectiveness, Safety

Outcome measures

Primary outcome

There are no pre-defined pass or fail criteria for evaluating the study objectives. Endpoints were selected to enable the sponsor, its safety committees, and regulatory agencies the ability to compare estimates obtained from this study to estimates from studies of other comparable procedures and devices. Objectives and endpoints were selected based on input from medical advisors experienced in related procedures and studies of other replacement valves and devices used to treat mitral regurgitation.

Secondary outcome

* Length of ICU stay

* Length of hospital stay

* 30 day mortality

* 3-month mortality

Study description

Background summary

The purpose of this expanded clinical study is to evaluate the performance and safety of the Tendyne Mitral Valve System in the treatment of severe mitral regurgitation in patents with functional disability greater than or equal to NYHA Class II, who are not suitable candidates for surgical replacement with otherwise available devices. The data gathered in this study may be used to support conformity requirements for CE Mark of the Tendyne system.

Study objective

Primary Safety Objective : To evaluate one month procedural and device safety of the Tendyne Bioprosthetic Mitral Valve System.

Primary Safety Endpoint :
Device success and freedom from the following device- or procedure-related serious adverse events (SAEs) at 30 days post implant, as classified by the Clinical Events Committee (CEC):
* Cardiovascular death
* Reintervention caused by valve-related dysfunction
* Disabling stroke
* Myocardial infarction (MI)
* Life-threatening bleeding
* Renal failure requiring dialysis
* Other device-related SAEs
* Other procedure-related SAEs
Stroke and MI classifications will be per the Valve Academic Research Consortium - 2 (VARC-2). Life-threatening bleeding classifications will be per the Bleeding Academic Research Consortium (BARC) consensus (Type 2, 3, and 5).

Secondary Safety Objective :
To evaluate long-term safety of the Tendyne Bioprosthetic Mitral Valve System.

Secondary Saety Endpoint :
Through two years post implant:
* Device success and,
* No device or procedure related SAEs

Primary Performance Objective :
To evaluate the performance of the Tendyne Mitral Valve System

Study design

Nonclinical assessments, pre-clinical data, and acute clinical study data have been used to evaluate the Tendyne Bioprosthetic Mitral Valve System design concept. This study is required to collect further data.
This study is a single-arm, multicenter study. The subjects will be individuals who have symptomatic mitral valve regurgitation and meet eligibility criteria.

Intervention

NA

Study burden and risks

Patients who are contraindicated for mitral valve replacement surgery - no open-heart surgery - less invasive access leads to lower operative risk -

the use of cardiopulmonary bypass carries several risks will be avoided

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

Subjects must meet ALL of the following criteria:
1. Severe mitral regurgitation of primary or secondary etiology.
2. New York Heart Association (NYHA) functional Class >= II. If Class IV, patient must be ambulatory.
3. Heart team determines patient is not a suitable candidate for traditional surgical treatment.
4. Age 18 years or older.

Exclusion criteria

Subjects will be excluded if any of the following criteria are met:
1. Severe mitral annular calcification, severe mitral stenosis, valvular vegetation or mass.
2. Left Ventricle (LV) or Left Atrium (LA) thrombus.
4. Left ventricular ejection fraction (LVEF) less than 30% by echocardiogram.
5. Left Ventricular End Diastolic Diameter (LVEDD) > 7.0 cm.
6. Prior surgical or interventional treatment of mitral or aortic valves
9. Myocardial Infarction (MI) within 30 days of the planned implant procedure.
10. Symptomatic, unresolved multi-vessel or unprotected left main coronary artery disease requiring stenting or Coronary Artery Bypass Grafting (CABG).
12. Unresolved severe symptomatic carotid stenosis (> 70% by ultrasound).
14. Severe tricuspid regurgitation or severe right ventricular dysfunction.
15. Hypertrophic or restrictive cardiomyopathy, constrictive pericarditis or any other structural heart disease causing heart failure other than dilated cardiomyopathy of either ischemic or non-ischemic etiology.
17. History of endocarditis within six months of planned implant procedure.
21. Patient has pulmonary arterial hypertension (fixed PAS >70mmHg).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2018
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Tendyne Bioprosthetic Mitral Valve System

Registration:	No

Ethics review

Approved WMO Date:	22-09-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-06-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT02321514
CCMO	NL59117.100.16