Clinical Evaluation of the Edwards Lifesciences Monarc system for the treatment of Mitral Regurgitation

Published: 16-11-2009
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To demonstrate the safety, efficacy, and performance of the Edwards Lifesciences MONARCTM system for the treatment of functional mitral regurgitation

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON33127

Source
ToetsingOnline

Brief title
Evolution II

Condition

- Cardiac valve disorders

Synonym
heartvalve dysfunction, mitralis regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: Edwards Lifesciences SA
Source(s) of monetary or material Support: Edwards Lifesciences LLC

Intervention

Keyword: Mitral Regurgitation, Monarc System

Outcome measures

Primary outcome

The primary safety endpoint is the individual rate of the following events:

Death, Myocardial Infarction (Q-wave or Non-Q-wave having total CK >2X normal with any CKMB > normal or elevated Troponin above institution*s upper level) and Cardiac tamponade within 30 days of date of implantation.

The primary efficacy endpoint is the percentage of subjects with a one-grade or greater reduction in severity of mitral regurgitation at 6 and 12 months (compared to baseline).

Secondary outcome

Percentage of subjects with MR severity of 2+ of less.

Percentage of subjects with a one-grade of greater reduction in severity of mitralregurgitation.

Frequency of rehospitalization for CHF.

Hemodynamic Parameters Evaluation via TTE.

Clinical funcionale status evaluation.

Quality of Life Assessment.

Study description

Background summary

Treatment options for functional MR in patients with heartfailure are limited. Surgery is associated with a high rate of complications. Annuloplasty throught

a percutaneous approach involving a device inserted into the coronary sinus has proven to be possible. This offers patients with heartfailure a chance to treat functional MR without the risk of open heart surgery.

Study objective

To demonstrate the safety, efficacy, and performance of the Edwards Lifesciences MONARCTM system for the treatment of functional mitral regurgitation

Study design

Multi-center, prospective, non-randomized study

Intervention

Implant Edwards Monarc Lifesciences system

Study burden and risks

Please refer to par. 2.3, pag. 12-14 of the protocol.

Contacts

Public
Edwards Lifesciences SA

Route de L'Etraz 70
1260 Nyon
CH
Scientific
Edwards Lifesciences SA

Route de L'Etraz 70
1260 Nyon
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- functional mitral valve regurgitation
- ischemic or idiopathic cardiomyopathy
- NYHA Class II-IV
- Moderatre to severe mitral regurgitation
- Ability to perform 6 minute walk: 150-450 meters

Exclusion criteria

- subjects who are eligible for biventricular pacing leads within the coronary sinus
- active endocarditis
- prior mitral valve repair of replacement
- serum creatinine leven > 2.0mg/dl
- allergy to anticoagulation medications or contrast media
- aortic valve disease that requires surgical intervention

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Monarc system
Registration:	No

Ethics review

Approved WMO Date:	16-11-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-03-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL28930.041.09