

# 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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Cardiac valve disorders
<b>Study type</b>	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

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### **Scientific**

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## **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
- Moderate 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 or replacement
- serum creatinine level > 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**

CCMO

**ID**

NL28930.041.09