# Cardioband Adjustable Annuloplasty System For Transcatheter Repair of Mitral Valve Regurgitation

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The objective of this study is to evaluate the performance and safety of the Cardioband Adjustable Annuloplasty System for repair of functional mitral regurgitation.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Cardiac valve disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46895

**Source**
ToetsingOnline

**Brief title**
Cardioband For Transcatheter MV Repair

### Condition

- Cardiac valve disorders

**Synonym**
mitral valve regurgitation

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Valtech Cardio LTD
**Source(s) of monetary or material Support:** Valtech Cardio LTD

## Intervention

**Keyword:** Functional, Mitral valve, Transcatheter

## Outcome measures

### Primary outcome

Safety:

* Overall rate of Major Serious Adverse Events (SAEs)* and serious adverse device effects (SADE) until hospital discharge and at post-operative 30 days.

* Death, myocardial infarction, cardiac tamponade, device related cardiac surgery, stroke

Performance

* Technical success rate of the implantation of the Cardioband

* Technical feasibility of Cardioband adjustment

* Cardioband ability to reduce mitral valve regurgitation (MR) Intra-procedure, at hospital discharge, and at 30 days.

### Secondary outcome

Safety:

* Overall rate of Major Serious Adverse Events (SAEs) and serious adverse device effects (SADE) until 12 months

Performance:

* MR Severity at 6 and 12 months

* Change in 6 MWT in 6 and 12 months

* Change in quality of life (MLHFQ) at 6 and 12 months*

# Study description

### Background summary

The current state of the art management of severe mitral regurgitation is surgical mitral valve repair, either with open chest surgery or mini-thoracotomy. However, standard surgical approaches requiring cardiopulmonary bypass are suitable for patients with low or moderate surgical risk; thus many patients are denied surgery because of unfavorable risk-benefit balance. The EuroHeart Survey conducted by the ESC showed that one half of patients with severe mitral regurgitation were denied surgical treatment because they were felt to be at too high risk for surgery by the referring physician. Such patients are usually elderly and have co-morbidities. Thus, there is a need for novel devices enabling interventional cardiologists and cardiothoracic surgeons to perform mitral annuloplasty in a transcatheter fashion. Cardioband replicates established surgical techniques for mitral repair (e.g., annuloplasty ring/bands), using transfermoral approach. In addition, Cardioband is implanted without sutures and adjusted on the beating heart. Therefore, the Cardioband System is expected to allow for treatment of patients that would otherwise not undergo mitral valve repair due to the invasiveness of current techniques. In addition, due to its size adjustability capabilities under beating heart, it enables to individualize the repair and thus may improve the outcome.

### Study objective

The objective of this study is to evaluate the performance and safety of the Cardioband Adjustable Annuloplasty System for repair of functional mitral regurgitation.

### Study design

A single arm, multi-center, prospective study with intra-subject comparisons. This study will enrol up to 30 subjects.

### Intervention

Cardioband is implanted via transseptal catheterization. Briefly: Cardioband is fixated with anchors along the posterior mitral annulus under fluoroscopic and Transoesophageal echocardiographic guidance. After implant deployed, implant size adjustment is performed under echocardiographic guidance.

**Study burden and risks**

Every medical procedure carries risks. Since the Cardio Band an experimental tool, some of these risks are not known. However, the doctor takes every precaution to minimize any risks.

Those risks associated with the implantation of the CARDIO BAND - ring are similar to those of conventional percutaneous mitral valve reconstructions.

* complications associated with anesthesia
* allergic reaction to a drug
* an inflammation of the lining of the heart ( endocarditis)
* pain
* groin bleeding
* infection
* myocardial infarction
* stroke
* blood clot
* heart failure
* abdominal pain
* cardiac arrhythmia
* fluid in the pericardium ( pericardial effusion )
* shortness of breath due to fluid in the lungs ( cardiac decompensation )
* small clots that occur on the implant itself and into your bloodstream may end up
* anemia
* tissue damage
* perforation of the blood vessel or portion of the heart
* failure of the medical device - a surgery may be required to explant the device
* death

As with other mitral rings , the Cardio Band ring can over time become impaired under the influence of chemicals present in the body ( corrosion ) or due to physical stress ( eg high blood pressure ) . As a result, a new surgical intervention, if any, must be done to remove the ring.

(*) At each participating site, a cardiac surgeon is being trained on Cardioband implant removal. The decision will be made upon the physician discretion. The Cardioband does not prevent any future treatment, in the unwanted case of failure the patients can stay under a clinical follow up, undergo Mitraclip procedure or be referred to surgery.

Important information for women
Women who are pregnant or breastfeeding cannot take part in this study .

Radiation
The length of time and exposure to radiation during the implant will be minimized. The amount of radiation is about the same as for those patients that would be treated with a MitraClip.

Benefits
Potential benefits for patients in whom the device is implanted, include the following:
* less tired or weak
* less chest pain
* in contrast to other rings, the CARDIO BAND-ring is inserted by means of a transfemoral surgery. That means it is inserted through the femoral vein. For the implantation of the valve, the chest does not need to be opened. This may shorten the healing time and hence the time the patient is in hospital after surgery.
* CARDIO BAND ring is implanted while the heart is beating. During implantation, the physician has the ability to adapt the CARDIO BAND ring to the size of your heart valve. The expectation is that this increases the clinical benefits and new operations are not necessary because of residual leakage of the valve.
* Currently there is one method for the treatment of leaking mitral valve in patients for whom open heart surgery entails a high risk available, namely the mitral clip. If a patient does not qualify for a MitraClip, treatment with medication would be the only remaining option; Thus, for those patients enrolled in this study, treatment by means of the cardio-band can be considered a benefit.

This research may also mean an improvement for the future treatment of heart failure.

## 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

* Age > 18 years
* Moderate to severe functional MR
* Symptomatic Patients (NYHA ClassII-IV) despite optimal medical therapy , including CRT if indicated.
* LVEF * 25%, LVEDD * 70mm
* Subject is high risk to undergo MV surgery (as assessed by a cardiac surgeon and a cardiologist at the site, and according to ESC/EACTS guidelines on the management of valvular heart disease)
* Transseptal catheterization and femoral vein access is determined to be feasible
* Subject is able and willing to give informed consent and follow protocol procedures

## Exclusion criteria

* Active bacterial endocarditis
* Severe organic lesions with retracted chordae or congenital malformations with lack of valvular tissue
* Heavily calcified annulus or leaflets
* Subjects in whom transesophageal echocardiography is contraindicated
* Untreated clinically significant CAD requiring revascularization
* Any percutaneous coronary, carotid, endovascular intervention or carotid surgery within 30 days or any coronary or endovascular surgery within 3 months
* CVA or TIA within 6 months or severe carotid stenosis (>70% by Ultra sound)
* Renal insufficiency requiring dialysis
* Life expectancy of less than twelve months
* Patient is pregnant (urine HCG test result positive) or lactating
* Known sensitivity or allergy to Nickel or Chromium
* Known sensitivity or contraindication to procedural medications which cannot be

adequately managed medically
* Bleeding or clotting disorders
* Subject is participating in concomitant research studies of investigational products
* Pulmonary hypertension >70mmHg at rest
* Mitral valve anatomy which may preclude proper device treatment
* Right-sided congestive heart failure with echocardiographic evidence of severe right ventricular dysfunction and severe tricuspid regurgitation

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-01-2016 |
| Enrollment: | 10 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Generic name: | Cardioband Adjustable Annuloplasty system |
| Registration: | No |

# Ethics review

Approved WMO

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|---|---|
| Date: | 09-12-2014 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

Approved WMO

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|---|---|
| Date: | 17-08-2015 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 02-10-2018 |
| 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 | NCT01841554 |
| CCMO | NL46113.100.14 |