SAFETY AND PERFORMANCE OF THE TRIALIGN PERCUTANEOUS TRICUSPID VALVE ANNULOPLASTY SYSTEM (PTVAS) FOR SYMPTOMATIC CHRONIC FUNCTIONAL TRICUSPID REGURGITATION

Published: 27-07-2017
Last updated: 12-04-2024

To assess the safety and performance of the Trialign System for the treatment of symptomatic chronic functional tricuspid regurgitation in patients with a minimum of moderate tricuspid regurgitation.

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

Summary

ID

NL-OMON45353

Source
ToetsingOnline

Brief title
SCOUT-II

Condition

- Cardiac valve disorders

Synonym
symptomatic chronic functional tricuspid - leakage of the right heartvalve

Research involving
Human

Sponsors and support

Primary sponsor: Mitralign Inc.
Source(s) of monetary or material Support: Industry: Mitralign Inc.

Intervention

Keyword: Percutaneous Valve Annuloplasty System, Pledgeted sutures, Tricuspid Regurgitation

Outcome measures

Primary outcome

Primary Endpoint: Incidence of all-cause mortality at 30 days.

Secondary outcome

Technical success, defined as freedom from death at 30 days with;

1) successful access, delivery and retrieval of the device delivery system;

2) deployment and correct positioning of the intended device(s) which is

maintained and;

3) no need for additional unplanned or emergency surgery or re-intervention

related to the device or access procedure

Echocardiographic variables assessed by the Echocardiographic Core Lab at

baseline and 30-days reflecting the severity of tricuspid pathology and the

response to the Trialign device:

1) Native Tricuspid valve morphology:

*- Tenting Height (maximum, any view)

*- Tenting Area (maximum, any view)

*- Quantification of tricuspid valve and annular area

2) Tricuspid regurgitation as determined by echocardiographic methods at

baseline and 30 days.

- PISA (Proximal Isovelocity Surface Area) method

- Quantitative flow method

3) Percent tricuspid regurgitation from baseline to 30-days

Rate of adverse events, including serious adverse events

Clinical Status Endpoints:

1) New York Heart Association (NYHA) classification

2) Six-minute walk test (6MWT)

3) Minnesota Living with Heart Failure Questionnaire (MLWHF)

4) EuroQol five dimensions questionnaire (EQ-5D)

Change from baseline in clinical status endpoints and echocardiographic variables assessed by the Echocardiographic Core Lab will be measured at discharge, 1, 3, 6, 12, 24, 36, 48 and 60 months post procedure.

Study description

Background summary

Tricuspid Regurgitation (TR) is an important disease in which the efficiency of the right ventricle is reduces, leading to several symptoms such as: fatigue, anorexia, elevated jugular venous pressure, hepatomegaly, ascites, peripheral edema, skin ulcerations, dilation of the right atrium, kidney disease and chronic atrial fibrillation. These symptoms reduce the quality of life of the patients.

Tricuspid regurgitation often exists in a setting of left ventricular

dysfunction and associated mitral valve disease.
The current treatment is often surgical repair of the tricuspid valve, however this is only recommended to patients who also have mitral valve disease requiring surgical treatment. So patients suffering from TR, but that are not yetsevere enough to have surgical treatment of the mitral valve, often are not eligible for the current treatment of surgical repair or replacement.
Therefore there is a large unmet need to new procedures and medical devices for minimal invasie repair of the tricuspid valve, so that these patients can be treated and hopefully their quality of life can be improved.

The study is designed to assess the safety and performance of the Trialign System for the treatment of symptomatic chronic functional tricuspid regurgitation in patients with a minimum of moderate tricuspid regurgitation

Study objective

To assess the safety and performance of the Trialign System for the treatment of symptomatic chronic functional tricuspid regurgitation in patients with a minimum of moderate tricuspid regurgitation.

Study design

Prospective, single-arm, multi-center study (not randomised, not blinded) in up to 60 patients in up to 15 sites in Europe and US.

Intervention

Trialign Percutaneous Tricuspid Valve Annuloplasty System (PTVAS)

Trialign PTVAS System is designed to perform a percutaneous suture annuloplasty of the tricuspid annulus to treat chronic functional tricuspid regurgitation. The Trialign PTVAS procedure utilizes catheters and wires to deliver up to two sets of -pledgeted sutures across the tricuspid annulus near the septal/posterior and the posterior/anterior commissures. Each set of implants is pulled together to plicate the posterior tricuspid annulus.

The system will be delivered percutaneously via the right internal jugular vein. The procedure will be guided by fluoroscopy and trans-esophageal echocardiography.

The Trialign PTVAS System is intended for the treatment of symptomatic chronic functional tricuspid regurgitation in patients with moderate to severe tricuspid regurgitation.

Study burden and risks

In-vitro, in-vivo, and biocompatibiltiy testing has identified and mitigated all known possible risks. The overall outcome of animal studies confirmed that placement of the Trialign device was feasible, safe and achieved its intended effect: reduction in annular diameter. Finally,
early experience in in the FDA early feasibility study and the Special Access patient experiences has demonstrated safety and feasibility of the Trialign device. The SCOUT II is now designed to assess the safety and performance of the Trialign PTVAS in a larger patient population. Based on all the evidence assembled to date, we believe that the potential benefit of participation in the SCOUT II Study clearly outweighs the potential risks.

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

1. >=18 and <=85 years old
2. New York Heart Association (NYHA) Class II, III or ambulatory IV
3. Symptomatic despite Guideline Directed Medical Therapy (GDMT) for at least 1 month; including diuretics
4. The patient is at high risk for open heart valve surgery
5. The heart team recommends tricuspid annuloplasty, in accordance with the recommendations of the 2012 ESC Valve Guidelines
6. Patient or legal guardian understands the study requirements and the treatment procedures and provides written Informed Consent before any study-specific tests or procedures are performed
7. Patient is willing and able to comply with all specified study evaluations

Exclusion criteria

1. History of heart transplant
2. Severe uncontrolled hypertension (SBP >= 180 mmHg and/or DBP >= 110 mmHg)
3. Previous tricuspid valve repair or replacement (including artificial valve)
4. Presence of LVAD, trans-tricuspid pacemaker or defibrillator leads
5. Active endocarditis
6. Severe coronary artery disease

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2017
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Trialign Percutaneous Tricuspid Valve Annuloplasty System (PTVAS)
Registration:	No

Ethics review

Approved WMO Date:	27-07-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-11-2017
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
CCMO	NL60930.042.17