Percutaneous Treatment of Tricuspid Valve Regurgitation With the TriCinch System*

Published: 26-04-2016
Last updated: 20-04-2024

To evaluate the safety and performance of the TriCinch System* in the treatment of functional tricuspid regurgitation

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

Summary

ID

NL-OMON43420

Source
ToetsingOnline

Brief title
PREVENT Study

Condition

- Cardiac valve disorders

Synonym
Percutaneous tricuspid valve repair, repair leaking heart valve.

Research involving
Human

Sponsors and support

Primary sponsor: 4Tech Cardio Ltd.
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Percutaneous Treatment, tricuspid valve repair

Outcome measures

Primary outcome

Safety:

-Acute safety at 30 days, defined as freedom from device related Major Adverse Events (MAE): death, Q-wave myocardial infarction, cardiac tamponade, cardiac surgery for failed TriCinch implantation, stroke, or septicaemia.

Performance:

- Acute device delivery success.

- Ability to reduce tricuspid regurgitation by at least 1 degree immediately following implantation of the TriCinch device assessed by means of quantitative echo-cardiographic parameters.

Secondary outcome

Safety:

- Rate of device related Major Adverse Events (MAE) at 3 and 6 months.

Performance:

- Ability to maintain tricuspid regurgitation respect to baseline at 3 and 6 months post-procedure.

- Quality of life assessment at 6 months

Study description

Background summary

The tricuspid valve may malfunction due to structural malformation secondary to other cardiac pathology or due to hardware through the valve. The most common presentation of TR is secondary to cardiac valvular pathology (mostly mitral valve disease) on the left side of the heart. As pulmonary hypertension develops, leading to right ventricular dilatation, the tricuspid valve annulus will dilate. The circumference of the annulus lengthens primarily along the attachments of the anterior and posterior leaflets. The septal leaflet is fixed between the fibrous trigones, preventing lengthening. As the annular and ventricular dilatation progresses, the chordal papillary muscle complex becomes functionally shortened. This combination prevents leaflet apposition, resulting in valvular incompetence.

The TriCinch System* percutaneous catheter-based device is designed for tricuspid valve repair in order to decrease effective cross-sectional area and relieve symptoms in patients with tricuspid valve regurgitation.

The 4TECH TriCinch System* implantation targets an unmet clinical need by offering benefits that may include: treatment for high risk patient not suitable for open-heart surgery, reduced pain, reduced risk of infection, shorter hospital stay, faster recovery, less scarring, and to avoid the need for reoperation or
replacement of the valve.

Study objective

To evaluate the safety and performance of the TriCinch System* in the treatment of functional tricuspid regurgitation

Study design

Prospective, non-randomized, single-arm, multi-centres and open trial.

Intervention

The TriCinch System* is a percutaneous catheter-based device for tricuspid valve repair. The TriCinch System* involves the placement of a novel tricuspid implant in order to decrease effective cross-sectional area and relieve symptoms in patients with tricuspid valve regurgitation. The female lock is designed to couple with the male lock. Tension is applied to the embedded implant to achieve coaptation of the leaflets of the Tricuspid valve and this

tension is maintained in the system through deployment of the stent.

Study burden and risks

Most of the test which are conducted during the study are standard of care. The pregnancy test, blood tests at 30d, 90d en 6m, and the chest x-ray at 30 days are study specific

Risk and burden:
Subject participation in this trial involves the standard risks for trans catheter treatments of the heart. There are additional potential risk that are cause by the use of the TriCinch device. All of these risks are analyzed and controlled by 4TECH, in compliance with ISO 14971.

Next to the standard risk involved in the repair of the tricuspid heart valve, risks specifically associated to the TriCinch System* include, but may not be limited to the following:
- Failure of anchoring implant in the desired area of the tricuspid valve (early or late)
- Failure of placing the stent in the vena cava (early or late)
- Unsuccessful tricuspid regurgitation reduction
- Tissue damage from insertion and removal of the delivery system
- Acute or chronic lesions

The 4TECH TriCinch System* is a medical device that will enable physicians to perform tricuspid valve repair while the heart is beating as an alternative to the open chest, arrested heart approach. The 4TECH TriCinch System* thus offers an alternative treatment to the open heart surgery where the heart is stopped which can offer significant potential benefits compared to existing treatments, in particular for the treatment of high-risk patient..
The expected risks are comparable to the risks associated to those of standard-transkatheter treatments of the heart and are compensated by the potential benefits.

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. Functional symptomatic tricuspid regurgitation (TR) 2+ to 4+ on a scale of 4+ (moderate to severe,
according to semi-quantitative echocardiographic color flow doppler evaluation)25 with symptoms such
as fluid retention and severe oedema requiring use of diuretics, liver stasis, and severe dilatation of the
tricuspid annulus (ie, annular diameter greater than 40 mm) confirmed by echocardiography
2. By subject signed and dated approved subject informed consent form prior to any study related procedure
3. Available and able to return to the study site for post-procedural follow-up examination.
4. Eighteen (18) years of age or older.

Exclusion criteria

1. Requirement for concomitant cardiac procedure (other than atrial fibrillation correction surgery,
closure of PFO (Patent Foramen Ovale) or ASD (Atrial Septal Defect), or PTCA (percutaneous treatment of coronary artery) or CAD (coronary artery bypass surgery) from 1 to 3 months after or
before other procedure.
2. Presence of any known life threatening (non-cardiac major or progressive disease), non-cardiac disease
that will limit the subject*s life expectancy to less than one year.

3. Cerebro-vascular event within the past 6 months.
4. History of mitral/tricuspid endocarditis within the last 12 months.
5. Organic tricuspid disease
6. Contraindication or known allergy to device*s components, aspirin, anti-coagulation therapy or
contrast media that cannot be adequately premedicated.
7. Severe hypertension (SBP >= 180 mmHg and/or DBP >= 110 mmHg, measurement done by
sphygmomanometer with stethoscope, allow the patient to sit for at least 5 minutes before beginning
BP measurements)26.
8. Female patient is pregnant (urine HCG test result positive) or lactating.
9. Known alcohol or drug abuser.
10. Currently participating in the study of an investigational drug or device.
11. At heart team's judgement, patient IVC dimension is not adequate for device implantation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2016
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	TriCinch System for catheter-based device delivery for tricuspid valve repair
Registration:	No

Ethics review

Approved WMO Date:	26-04-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-10-2016
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	NCT02098200
CCMO	NL56206.100.15

Study results

Date completed:	25-04-2017
Actual enrolment:	5

Summary results
Trial is onging in other countries