Clinical Trial Evaluation of the Percutaneous 4Tech TriCinch Coil Tricuspid Valve Repair System

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Primary objective: To generate safety and performance data for the 4Tech TriCinch Coil System in symptomatic patients suffering from moderate to severe functional tricuspid regurgitation with annular dilatation. Secondary objective: To evaluate the...

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

Summary

ID

NL-OMON50495

Source
ToetsingOnline

Brief title
TriCinch Coil study

Condition

- Cardiac valve disorders

Synonym
Functional tricuspid regurgitation with annular dilatation.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Functional tricuspid valve regurgitation., Percutaneous tricuspid valve repair.

Outcome measures

Primary outcome

All-cause mortality of the primary endpoint cohort at 30 days post procedure.

Secondary outcome

• Technical success defined as (per MVARC) at post-procedure and 30 days post-procedure: absence of procedural mortality; and successful access, delivery, and retrieval of the device delivery system; and successful deployment and correct positioning of the first intended device; and freedom from emergency surgery or reintervention related to the device or access procedure.

• Number of individual adverse events related to the system or procedure at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months, also expressed as a percentage.

• Echocardiographic improvement at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months compared to Baseline by means of echocardiographic semi-quantitative and quantitative measures (e.g. TV annular diameter, TV area, vena contracta, PISA EROA, Quantitative EROA, TV Regurgitant Volume, RA, RV, IVC dimensions, TAPSE). The independent Echo core lab measurements will be used to evaluate this secondary endpoint.

• Functional improvements at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months as compared to Baseline for New York Heart Association (NYHA) classification, Exercise tolerance (Six Minute Walk Test) and Quality of

Life evaluation (Kansas City Cardiomyopathy Questionnaire).

• Rate of Heart Failure event post-procedure defined as a heart failure hospitalization or a heart failure hospitalization equivalent at three (3), six (6), twelve (12) and twenty-four (24) months (further details in Section 6.2.5.)

• Changes in peripheral oedema at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months

• New onset of Atrial Fibrillation at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months

• Change in average dosages of concomitant cardiac medications (including diuretics) at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months

• Kidney function at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months as compared to Baseline

• Change in NT-ProBNP at 30 days, three (3), six (6), twelve (12) and twenty-four (24) months as compared to Baseline

• Procedure time

• Radiation dose during the procedure

Study description

Background summary

The goal of this clinical study is to evaluate the safety and performance of the TriCinchTM Coil System as a new method to treat leaking tricuspid valves which cause regurgitation (backflow of blood).

A leaking Tricuspid valve may be caused by various reasons. Often, the cause can be a different valve disease of the left side of the heart but also it can

be unknown what the cause is.
When high blood pressure (hypertension) develops in the arteries of the lungs it can lead to dilation of the right heart chamber and the tricuspid valve annulus becomes enlarged (dilates). This can result in incorrect positioning of the tricuspid valve leaflets which prevents the valve from functioning properly. Today, "open heart" surgery is the standard treatment for this disease. The risks associated with this surgical procedure are high for certain patients. Unlike standard surgical treatment, the TriCinch* Coil System offers a percutaneous treatment (access through the vein at the groin) to treat the leaking tricuspid valve, without the need for surgical intervention.

Study objective

Primary objective:

To generate safety and performance data for the 4Tech TriCinch Coil System in symptomatic patients suffering from moderate to severe functional tricuspid regurgitation with annular dilatation.

Secondary objective:

To evaluate the long-term safety of the device and the effects of the device on echocardiographic, functional and quality of life parameters.

Study design

Multi-center, prospective, single-arm, non-randomized study

Intervention

On the day of the TriCinch* Coil System procedure, the physical condition of the patient will be evaluated, and an electrocardiogram (ECG) will be taken. The procedure may be done under a general anaesthetic or with a local anaesthetic and sedation. The type of anaesthetic used for procedure and the reason why will be discussed between the patient and the doctor. During the procedure, the tricuspid valve leakage will be assessed using TOE (transoesophageal echocardiography - an ultra sound using a probe which is placed in your oesophagus) &/or intracoronary echocardiogram (ICE an ultrasound placed inside the heart) and angiography (dye injections) to enable the doctors to view images of the heart & the device. Local anaesthetic will be injected into the groin to numb the area. First, a small volume of gas (carbon dioxide) is injected so the area surrounding the heart can be appropriately visualized. Then, the system is inserted through a vein in the groin (femoral vein) and is then passed through the inferior vena cava (large vein) which leads to the right side of the heart. The tricuspid valve is then accessed and the TriCinch* Coil System will be implanted. During the procedure, a pericardial

drain (needle inserted through the chest wall) is placed in order to remove any abnormal fluid accumulation around the heart. This drain will stay in place for 24h if no fluid accumulates around your heart; or longer until all fluid accumulated around your heart has been removed.

Study burden and risks

Participation in this clinical trial may involve certain risks associated with medications / treatments and/or linked to the medical exams:
• Allergic reaction
• Anaphylactic shock
• Aortic dissection
• Aortic insufficiency
• Arterial dissection
• Cardiac arrhythmia, including atrial fibrillation and compromised AV node
• Cardiac tamponade/pericardial effusion
• Coronary artery obstruction
• Coronary artery puncture
• Delay in treatment
• Dissection, any vessel
• Dyspnea
• Esophagus irritation/perforation
• Gastro-intestinal bleeding
• Heart failure exacerbation
• Hematoma, haemorrhage or bleeding
• Hemodynamic deterioration
• Hemolysis
• Infection
• Inferior vena cava puncture
• Inflammation
• Myocardial infarction
• Myocardial ischemia, mild, moderate or severe
• Peripheral ischemia
• Pneumothorax
• Prolonged ventilation
• Prolonged exposure to fluoroscopic radiation
• Pseudo-aneurysm
• Pulmonary edema
• Pulmonary embolism
• Renal failure
• Renal insufficiency
• Right ventricular failure
• Septicemia
• Stroke or transient ischemic attack
• Tissue erosion
• Venous dissection
• Venous occlusion

• Venous perforation
• Venous thrombosis
• Ventricular arrhythmia, including ventricular tachycardia and fibrillation
• Vessel spasm

The potential risks specifically associated with the tricuspid valve procedures include, but may not be limited to, the following:
• Reoperation and explants;
• Residual or recurrent regurgitation requiring intervention; failure to reduce tricuspid regurgitation in the long term;
• Stenosis; hemolysis; atrioventricular block;
• Endocarditis; low cardiac output; right heart failure;
• Failure or degeneration of the natural valvular apparatus due to progression of disease;
• Inadequate repair of the valvular and sub-valvular structure
• Partial detachment/dislodgment (partial or full) of the coil or stent component from its site of attachment; migration or malposition;
• Malfunction of the coil or stent component due to distortion or fracture at the implant or physical or chemical deterioration of tensioning band components;
• Bleeding complications related to use of anticoagulant therapy;
• Device thrombosis; infection.

The risks associated specifically to the TriCinch Coil include, but may not be limited to the following:
• Failure of anchoring implant in the desired area of the pericardial space;
• Failure of placing the stent in the vena cava;
• Vessel perforation or tissue damage or vascular injury due to coil insertion or stent deployment;
• Unsuccessful adjustment during system tensioning;
• Unsuccessful tricuspid regurgitation reduction;
• Tissue damage from insertion and removal of the delivery system;
• Acute or chronic lesions.
• Needle insertion damage to heart wall from inadvertent exposure of needle.
• Pericardial effusion/tamponade from insufficient haemostasis around coil implant.

The risks associated with the pericardial drain (needle inserted through the chest wall) not covered above include, but may not be limited to the following:
• Right Ventricle to Abdomen fistula (abnormal connection between the abdomen and the lower right heart chamber)
• Haemoperitoneum (presence of blood in the peritoneal cavity)

The staff of the hospital's Cardiology Department will treat the patient with the appropriate care and skill to prevent the risks described above from occurring and, if they do occur, to resolve them adequately. Serious complications requiring emergency heart surgery will be addressed immediately. A heart surgery team is present and operational at the site 24 hours a day.

As with any device undergoing clinical investigation, there may be unforeseeable risks, which are not known at this time. Medical and/or surgical intervention may be required to correct clinical complications associated with the device procedure.

Radiation Exposure
Taking part in this trial will involve exposure to ionizing radiation, through fluoroscopic imaging to assist in the procedure to insert the 4 Tech TricinchTM Coil System device, as well as through a CT scan of the heart and through chest x-rays one month and 6 months following the procedure. The device implantation procedure and the cardiac CT scan procedure will be part of normal care whether or not the patient is participating in this trial, and only the radiation from the chest x-rays may be additional to the normal care.
The dose of radiation from all of these procedures could be up to 35 mSv. This dose of radiation is equivalent to approximately 17.5 years of natural background radiation to which we are all subjected.

POTENTIAL BENEFITS ASSOCIATED WITH PARTICIPATING IN THIS STUDY
The TriCinch* Coil System is a medical device that enables physicians to treat tricuspid valve leakage while the heart is beating, as opposed to an "open heart" approach, where the heart is stopped. Because this device is less invasive and avoids most of the complications associated with "open heart" surgery, it targets an unmet medical need and the benefits may include:
• a treatment for high-risk patients in whom open-heart surgery is contraindicated
• avoiding chest incisions;
• reduced pain;
• avoiding extracorporeal circulation and heart stoppage for the majority of patients;
• the ability to evaluate the results of treating tricuspid leakage while the heart is completely
functional at the end of the procedure, so that correction of the tricuspid leakage can be
optimized;
• shorter hospitalization and faster recuperation.
It is not possible to know in advance whether participating in the trial will benefit the patient or not, even if it is believed that there will very likely be an improvement in your symptoms. In any case, the data collected will be used to improve the features of the device and implantation procedure, which will help optimize the therapy for future patients suffering from this condition. The device was tested during preclinical studies and deemed appropriate for implantation in humans.

Contacts

Public
4 Tech Cardio Ltd

Ballybrit Business Park 3
Galway H91DT7C
IE
Scientific
4 Tech Cardio Ltd

Ballybrit Business Park 3
Galway H91DT7C
IE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Moderate to severe functional tricuspid regurgitation (TR) defined as:
• TR severity 2+ to 4+ (according to semi-quantitative echocardiographic color flow doppler evaluation), and
• Annular diameter >= 40 mm confirmed by echocardiography
2. >= 18 years old
3. Subject has read and signed the informed consent prior to study related procedures.
4. Willing and able to comply with all required follow-up evaluations and assessments.
5. The 'Heart Team' assessment recommends TriCinch Coil Implantation. NOTE: At this time, the Heart team will not recommend TriCinch Coil Implantation on patients with a history of cardiac surgery. For more information, refer to

Section 8.1.1.
NOTE 2: The Heart team will recommend TriCinch Coil implantation for patients classified as high-risk for open heart surgery. For more information, refer to Section 8.1.
6. New York Heart Associate Classification >= II.
7. Left Ventricular Ejection Fraction >= 30%.
8. Heart failure symptoms (such as fluid retention and severe oedema, liver stasis) despite on optimized medical therapy by the local heart team; at minimum subject on diuretic use
9. Subject has suitable anatomy for investigational device implantation as per imaging requirements

Exclusion criteria

1. Currently participating in another investigational drug or device study.
2. Subject with Systolic pulmonary arterial pressure (sPAP) > 60mmHg as measured by Transthoracic Echocardiography (TTE)
NOTE: In case the sPAP measured by TTE is 60 mmHg or more, a right heart catheter should be performed during screening to confirm whether or not the patient can be enrolled into the study
3. Subject requiring another cardiac procedure in the framework of the index procedure; subject requiring a percutaneous procedure within 30 days before or after the procedure or a cardiac surgical procedure within 3 months before or after the procedure
4. Moderate or Severe tricuspid valve stenosis (defined as a mean gradient >=5 mmHg at normal heart rate)
5. Aortic and/or pulmonic valve stenosis and/or regurgitation more than or equal to moderate
6. Mitral valve stenosis and/or regurgitation more than moderate
7. Intra-cardiac thrombus, mass or vegetation requiring active treatment
8. Implanted inferior vena cava (IVC) filter.
9. Prior tricuspid repair or tricuspid replacement
10. Known allergy to contrast media, silicone, PET, Co-Cr, stainless steel or nitinol that cannot be adequately pre-medicated
11. History of cardiac transplantation
12. Contraindication to Transthoracic/Transoesophageal Echocardiography (TTE/TOE).
13. Endocarditis or severe infection within 12 months of scheduled implant procedure
14. Myocardial Infarction (MI) or known unstable angina within the 30 days prior to the index procedure
15. Cerebro Vascular Accident within the previous 6 months
16. Hemodynamic instability or on IV inotropes
17. Contraindication to anticoagulant therapy and dual antiplatelet therapy
18. Bleeding disorders or hypercoagulable condition (at risk of blood clots)

19. Active peptic ulcer or active GI bleeding within 3 months of scheduled implant procedure
20. Severe renal impairment or on dialysis
21. Life expectancy less than 12 months.
22. Acute anemia
23. Chronic Oral Steroid Use >= 6 months
24. Pregnant or lactating female of childbearing potential with a positive pregnancy test 24 hours before any study-related radiation exposure
25. Pulmonary embolism within the last 6 months
26. Tricuspid Valve Tethering distance > 10 mm
27. Presence of trans-tricuspid pacemaker or defibrillator leads which are determined as immobile or interfering with the procedure, as evaluated by echocardiography.
28. Contra-indicated for blood transfusion or refuses transfusion
29. Patient undergoing emergency treatment
30. Patient without appropriate venous access

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2018
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	4Tech Transcatheter TriCinch Coil with 4Tech Delivery System
Registration:	No

Ethics review

Approved WMO Date:	04-12-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-06-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-01-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-03-2020
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	NCT03294200
CCMO	NL62459.100.17