Safety and Performance Evaluation of the AccuCinch Ventricular Repair System for the treatment of heart failure, with or without functional Mitral Regurgitation Due to Dilated Ischemic or Non-Ischemic Cardiomyopathy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON48568

Source
ToetsingOnline

Brief title
CORCINCH-EU

Condition

- Heart failures

Synonym
dilation of heart left ventricle, functional mitral regurgitation, Heart failure

Research involving

Human

Sponsors and support

Primary sponsor: Ancora Heart, Inc.
Source(s) of monetary or material Support: Manufacturer of the study device

Intervention

Keyword: Heart Failure, Mitral Valve Insufficiency, Ventriculoplasty

Outcome measures

Primary outcome

The performance and safety endpoints of the AccuCinch System will be assessed by monitoring the patient clinical status (recording of adverse events), assessing quality-of-life scores, and evaluating vital, cardiopulmonary, hematology, biochemistry and functional parameters, cardiopulmonary tests data during the visits within the follow-up period,

Also, see above in "Objectives of the study".

• Each of the individual primary safety endpoints will be evaluated. The analysis will be performed on the ITT patient population. There is a possibility that there will be sample bias in the patient selection process, due to the available commercial product (Mitraclip). Therefore, investigators are likely to choose patients who are older and more compromised to participate in this clinical study. Therefore, the characteristics of the population will be compared with previously reported, published series

Secondary outcome

Technical success and device success will be assessed in the IPP population;

reduction of MR and absence of technical of structural or functional failure

will be based on Imaging Core Laboratories evaluations of intraprocedural TEE

and postprocedural TTE or cardiac CT angiography when available. The proportion

of patients with technical and device success will be presented with 95%

confidence intervals.

Also, see above in "Objectives of the study".

Study description

Background summary

This clinical study will evaluate the safety and performance of the AccuCinch Ventricular Repair System for the treatment of heart failure and functional mitral regurgitation in symptomatic adult patients with or without functional mitral regurgitation (FMR) and left ventricular remodeling due to dilated cardiomyopathy (ischemic or non-ischemic etiology), who remain symptomatic despite optimized medical therapy.
Subjects with FMR must present with at least moderate FMR, a reduced ejection fraction (<=40%) and high operative risk as assessed by the Heart Team. The Heart Team may utilize established risk scores (STS, Euro-Score II) in conjunction with comorbidities as recommended by MVARC (frailty index; major organ system compromise not to be improved postoperatively; procedure specific impediments).
Subjects without FMR must present a markedly dilated left ventricle with LVEDD >= 55 mm and reduced ejection fraction (<=40%). These patients are not potential candidates for *conventional intervention*, because their mitral valve is not in need of repair or replacement. Therefore, AccuCinch represents the sole treatment option for these patients, who are not selected on the basis of high surgical risk.

Study objective

The primary safety endpoint is to evaluate a 30-day major adverse event (MAE) rate, where MAE is a composite of the following device- or procedure-related events:
• All-cause mortality
• Stroke

• Life-threatening bleeding (MVARC scale)
• Major vascular complications
• Major cardiac structural complications
• Myocardial infarction or coronary ischemia requiring PCI or CABG
• Stage 2 or 3 acute kidney injury (includes new dialysis)
• Severe hypotension, worsening of heart failure, or respiratory failure requiring intravenous pressors or invasive or mechanical heart failure treatments such as ultra*ltration or hemodynamic assist devices, including intra-aortic balloon pumps or left ventricular or biventricular assist devices, or prolonged intubation for >48 h.
• Emergency surgery or re-intervention related to the device or access procedure

Secondary Safety Endpoints evaluated at 30-day, 90-day, 180-day, 1-year and annually at year 2, 3, 4,and 5 (inclusive of unscheduled visits):
o Death, cardiac, non-cardiac
o Stroke
o Mitral valve reintervention or surgery
o Myocardial Infarction
o Any device related complication/dysfunction
o New atrial fibrillation (AF)
o New conduction disturbance requiring permanent pacemaker (PM)

• Secondary Performance Endpoints evaluated at 30-day, 90-day, 180-day, 1-year and annually at year 2, 3, 4, and 5 (inclusive of unscheduled visits):
o Technical success (measured at exit from catheterization laboratory or hybrid O.R.):
• Successful access, delivery, and retrieval of all AccuCinch catheters;
• Deployment and correct positioning of the intended AccuCinch implant; and
• No need for additional unplanned or emergency surgery or re-intervention related to the device or access procedure measured upon completion of the procedure.
o Device Success: Original intended device in place and no additional surgical or interventional procedures related to the device since completion of the original procedure (i.e., exit from the cath lab or hybrid O.R.)
• Structural performance: No migration, embolization, detachment, fracture, hemolysis, thrombosis or endocarditis; and no para-device complications (erosion, effusion requiring surgery or drainage or producing tamponade, damage to the MV apparatus)
o Improvement from baseline in NYHA functional class
o Improvement from baseline in 6MWT (Increase in distance (m))
o Improvement from baseline in Kansas City Cardiomyopathy Questionnaire (KCCQ) quality of life
o Freedom from re-hospitalizations or re-interventions for the underlying condition

Additional performance variables will be recorded and followed for bench-marking and/or ad-hoc analyses. Variables may include the following:

• Change in cardiac-related medications
• Composite mitral regurgitation (MR) grade
• % Ejection fraction (%EF)
• Proximal isovelocity surface area (PISA) effective regurgitant orifice area (EROA)
• Left ventricular end-diastolic volume (LVEDV) and index (LVEDVI)
• Left ventricular end-systolic volume (LVESV) and index (LVESVI)
• Left ventricular end-diastolic diameters (LVEDD)
• Left ventricular end-systolic diameters (LVESD)
• Left atrial volume (LAV)
• PISA radius
• Sphericity index
• Regurgitant volume (RV)
• Regurgitant fraction (RF)
• Cardiac output/index
• Tenting height
• Tenting area
• Coaptation length
• Vena contracta width and area
• Annular diameter (septal lateral and anteroposterior), circumference and area
• Intrapapillary muscle distance
• Stroke volume
• Left ventricular stroke volume
• Left ventricular outflow tract diameter (LVOTD)
• Pulmonary pressure
• Implant location

Study design

This is a prospective, non-randomized, single-arm, international, multicenter, safety and performance clinical investigation.

Intervention

Eligible subjects will receive treatment for their condition with the AccuCinch implant. The device will be implanted using the same technique as similar devices.
For a detailed description of the procedure please refer to the protocol pages 64-65 and to the Instructions for Use (IFU).

Study burden and risks

Since this is a new procedure, not all of the risks are known at this time. Potential procedural risks are the same as those associated with any femoral catheterization and percutaneous mitral valve implantation procedure, including bleeding, wound healing, infection, dislodgement, thrombosis and scarring from

the incision, as well as the standard risks associated with anesthesia (including an allergic reaction ranging from mild to life threatening, incomplete sedation, or heart rhythm abnormalities).

Mitral valve repair and LV volume reduction with the AccuCinch may result in one or more of the following benefits for patients at high risk for surgery decrease in mitral regurgitation, alleviation of symptoms related to mitral insufficiency or heart failure, increased functional capacity and better quality of life. It is reasonable to expect that the medical benefits of the AccuCinch will outweigh the risks but this need to be proven and the present study will collect clinical information to further confirm a favorable risk-benefit ratio.

For a detailed description of the risks, burden, benefits and risk-benefit analysis, please refer to chapter 7 of the study protocol.

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. Age >= 18 yrs
2. Subjects who present with heart failure with or without functional mitral regurgitation due to dilated cardiomyopathy of ischemic or non-ischemic etiology
a. For subjects with FMR severity of FMR: >= Moderate 2+
b. For subjects without FMR, LVEDD >= 55 mm
3. LVEF >=20% to <=40%. Patients with EF >40% are excluded
4. Symptom Status: NYHA II- IV (i.e., ambulatory)
5. Patients to be considered for the present study will be required to have received all appropriate guidelines-recommended medical therapies for at least 3 months prior to the enrollment with stable doses of drugs for at least 1 month
6. Surgical risk:
a) Voor patiënten met alleen FMR: Het Hart Team moet de patiënt als hoog risico evalueren en mag de bestaande risico scores gebruiken of comorbiditeiten om blijk te geven van hoge-risicofactoren. Hoog risico voor mitralisklepchirurgie wordt gedefinieerd met behulp van erkende risicoscores (STS, Euro-Score II) in combinatie met comorbiditeiten zoals aanbevolen door het MVARC (fragiliteitsindex; stoornis van belangrijke orgaansystemen die postoperatief niet verbetert; belemmeringen specifiek voor de ingreep) (MVARC deel 1).
b) Voor alle patiënten: de patiënt is geschikt voor cardiale chirurgie (namelijk, de patiënt is in een conditie die voldoende is voor een potentiele conversie naar open chirurgie in geval van procedurele complicaties). Dit criterium voegt een veiligheids niveau voor patiënten toe.
a. For patients with FMR only: The Heart Team must assess as high-risk and may utilize risk score or comorbidities to demonstrate high risk features. High risk for mitral valve surgery is defined utilizing established risk scores (STS, Euro-Score II) in conjunction with comorbidities as recommended by MVARC (frailty index; major
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organ system compromise not to be improved postoperatively; procedure specific impediments) (MVARC Part 1)
b. For all patients: Subject is eligible for cardiac surgery (namely, the patient is in a condition that allows a potential conversion to open surgery in case of procedural complications). This criterion adds a safety level for the patients.
7. Completion of all qualifying diagnostic and functional tests and agrees to comply with study follow-up schedule
8. Patients required to have an ICD are required to have ICD implant at least 1 month prior to enrollment

Exclusion criteria

1. Life expectancy <1 yr due to noncardiac conditions
2. NYHA functional class IV (i.e., non-ambulatory) or ACC/AHA stage D heart failure
3. Hypotension (systolic pressure <90 mm Hg) or requirement for inotropic support or mechanical hemodynamic support
4. Hypertrophic cardiomyopathy, restrictive cardiomyopathy, constrictive pericarditis, or any other structural heart disease causing heart failure other than dilated cardiomyopathy of either ischemic or non-ischemic etiology
5. Fixed pulmonary artery systolic pressure >70 mm Hg
6. Physical evidence of right-sided congestive heart failure with echocardiographic evidence of moderate or severe right ventricular dysfunction
7. Mitral valve anatomy which may preclude proper device treatment
8. Mitral valve area <4.0 cm2 (if new device therapy may further decrease the mitral orifice area)
9. Any prior mitral valve surgery or transcatheter mitral valve procedure
10. Stroke or transient ischemic event within 30 days
11. Modified Rankin Scale >= 4 disability
12. Need for emergent or urgent surgery for any reason or any planned cardiac surgery within the next 12 months
13. Untreated clinically significant coronary artery disease requiring revascularization
14. Severe symptomatic carotid stenosis (>70% by ultrasound).
15. Myocardial infarction <= 30 days
16. Any percutaneous cardiovascular intervention, cardiovascular surgery, or carotid surgery within 30 days
17. Tricuspid valve disease requiring surgery or severe tricuspid regurgitation (per ASE guidelines)
18. Aortic valve disease requiring surgery
19. Moderate or severe aortic valve stenosis or regurgitation
20. Aortic valve prosthesis
21. Fluoroscopic or echocardiographic evidence of severe aortic arch calcification, mobile aortic atheroma, intracardiac mass, thrombus, or vegetation
22. Need for any cardiovascular surgery (other than for MV disease)
23. Active endocarditis
24. Anatomical pathology/constraints preventing appropriate access/implant of the AccuCinch System (e.g., femoral arteries will not support a 20F system)
25. Known allergy to nickel, polyester, or polyethylene
26. Active infections requiring current antibiotic therapy
27. Currently participating in another investigational study
28. Subjects in whom transesophageal echocardiography is contraindicated or high risk
29. Renal insufficiency (i.e., eGFR of <30ml/min/1.73m2; Stage 4 or 5 CKD)
30. Subjects in whom anticoagulation or antiplatelet therapy is contraindicated

31. Any prior true anaphylactic reaction to contrast agents; defined as known anaphylactoid or other non-anaphylactic allergic reactions to contrast agents that cannot be adequately pre-medicated prior to procedure.
32. Implant or revision of any rhythm management device (CRT or CRT-D) or implantable cardioverter defibrillator within 1 month
33. Absence of CRT with class I indication criteria for biventricular pacing (left bundle branch block pattern and QRS duration >=150 ms)
34. Subjects on high dose steroids or immunosuppressant therapy
35. Any condition making it unlikely the patient will be able to complete all protocol procedures (including compliance with guideline directed medical therapy) and follow-up visits
36. Patient (or legal guardian) unable or unwilling to provide written, informed consent before study enrollment. This study excludes vulnerable populations as defined in protocol section 18.
37. Pregnant or planning pregnancy within next 12 months. Note: Female patients of childbearing potential need to have a negative pregnancy test performed within 14 days prior to intervention and be adherent to an accepted method of contraception

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):	11-03-2019
Enrollment:	28
Type:	Actual

Medical products/devices used

Generic name:	AccuCinch Ventricular Repair System
Registration:	No

Ethics review

Approved WMO Date:	08-11-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-12-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-06-2021
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	NCT03183895.
CCMO	NL62154.100.17

Study results

Date completed: 25-06-2020

Summary results
Trial ended prematurely