Randomized Clinical Evaluation of the AccuCinch® Ventricular Restoration System in Patients who Present with Symptomatic Heart Failure with Reduced Ejection Fraction (HFrEF): The CORCINCH-HF
Study

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The objective of this study is to evaluate the safety and efficacy of the AccuCinch Ventricular Restoration System in patients with symptomaticheart failure with reduced ejection fraction (HFrEF).

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

Summary

ID

NL-OMON53754

Source
ToetsingOnline

Brief title
The CORCINCH-HF Study (5019)

Condition

- Heart failures

Synonym
a condition that is caused by dilation of the wall of the pumping chamber of your heart

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiomyopathy, Heart Failure, Reduced Ejection Fraction

Outcome measures

Primary outcome

6-Month Primary Safety & Efficacy Endpoints (~250 subjects randomized 1:1):

• Safety Endpoint: (~125 Treatment group subjects)

Freedom from device- or femoral artery access-related major adverse events

(MAEs) through 6 months where MAEs are defined as the composite of:

a. All-cause death;

b. Stroke;

c. Myocardial infarction;

d. Need for non-elective cardiovascular surgical procedures to treat:

i. Femoral artery access events,

ii. Pericardial effusions or tamponade,

iii. Aortic valve damage,

e. Need for mechanical circulatory support for more than 24 hours due to

worsening heart failure or hemodynamic instability;

f. Acute kidney injury requiring renal replacement therapy

• Efficacy Endpoints

Change from baseline at 6 months:

a. Kansas City Cardiomyopathy Questionnaire Quality of Life Questionnaire

Overall Score (KCCQ-OS)

b. 6-Minute Walk Test (6MWT)

12-Month Safety & Efficacy Endpoints (~400 subjects randomized 1:1):

• Safety Endpoint: (~200 Treatment group subjects)

Freedom from device- or femoral artery access-related major adverse events

(MAEs) through 12 months where MAEs are defined as the composite of:

a. All-cause death;

b. Stroke;

c. Myocardial infarction;

d. Need for non-elective cardiovascular surgical procedures to treat:

i. Femoral artery access events,

ii. Pericardial effusions or tamponade,

iii. Aortic valve damage;

e. Need for mechanical circulatory support for more than 24 hours due to

worsening heart failure or hemodynamic instability;

f. Acute kidney injury requiring renal replacement therapy

• Efficacy Endpoint

A hierarchical composite endpoint at 12 months, evaluated using the Win Ratio

method:

a. All-cause death,

b. LVAD implant or heart transplant,

c. Number of heart failure hospitalizations,and

d. Change from baseline KCCQ-OS score

Secondary outcome

Secondary Safety & Efficacy Endpoints (~400 subjects randomized 1:1):

• Secondary Safety Endpoints

To be evaluated at 1-month, 3-month, 6-month, 12-month, 18-month and 2-year follow-up visits:

a. All-cause death or all-cause hospitalizations

b. All-cause death

c. All-cause hospitalizations

d. Incidence of all serious adverse events, including device and procedure-related complications

• Secondary Efficacy Endpoints

Changes from baseline to 1-month, 3-month, 6-month, 12-month,18-month and 2-year follow-up visits:

a. NYHA Functional Class

Changes from baseline to 1-month, 3-month, 12-month, 18-month and 2-year follow-up visits

a. KCCQ-OS

b. 6-Minute Walk Test

Changes from baseline and from post-procedure/pre-hospital discharge to 1-month, 3-month, 6-month, 12-month and 2-year follow-up visits as assessed by echo:

a. Left ventricular ejection fraction (LVEF)

b. Left ventricular end-diastolic volume (LVEDV)

c. Left ventricular end-systolic volume (LVESV)

To be evaluated at 1-month, 3-month, 6-month, 12-month, 18-month and 2-year

follow-up visits:

a. CV death

b. HF death

c. HF-related hospitalizations

Study description

Background summary

Reduced Ejection Fraction Heart Failure (HFrEF) has been singled out as an epidemic and is a staggering clinical and public health problem associated with significant mortality, morbidity, and healthcare expenditures, particularly among those aged >=65 years. After the diagnosis of HF, survival estimate is 50% at 5 years, and left ventricular dysfunction is associated with an increase in the risk of sudden death.

Study objective

The objective of this study is to evaluate the safety and efficacy of the AccuCinch Ventricular Restoration System in patients with symptomatic heart failure with reduced ejection fraction (HFrEF).

Study design

The CORCINCH-HF Study is a prospective, randomized, open-label, multicenter, international, clinical safety and efficacy investigation of the AccuCinch Ventricular Restoration System. The study will be conducted in two phases. Phase 1 will evaluate the safety of the AccuCinch treatment with respect to pre-defined MAEs compared to a pre-specified performance goal and the efficacy of the AccuCinch treatment as compared to the Control group with respect to quality of life (via Kansas City Cardiomyopathy Questionnaire overall score, KCCQ-Overall Score) and exercise tolerance (via 6-minute walk test distance, 6MWT), evaluated at 6 months of follow-up. Phase 2 will evaluate the safety of the AccuCinch treatment with respect to pre-defined MAEs compared to a pre-specified performance goal and the efficacy of the AccuCinch treatment using a hierarchical composite of death, left ventricular assist device use, the need for heart transplant, the total number of heart

failure hospitalizations and quality of life (by KCCQ-OS) compared to the Control group, evaluated at 12 months of follow-up.
Subjects will be randomized in a 1:1 ratio:
a) Treatment group: AccuCinch Ventricular Restoration System plus guideline-directed medical therapy (GDMT) (n~200)
b) Control group: Guideline-directed medical therapy (GDMT) (n~200)
Randomization will be stratified by study site and by ischemic versus nonischemic dilated cardiomyopathies.
The final primary endpoints of the study will be evaluated at 12 months. Subjects will be followed through 5 years. Control subjects will be given an opportunity to cross-over to device treatment after the 24-month visit if they still meet study entry criteria. Such subjects will be followed according to the same schedule of events as subjects initially randomized to the Treatment group for a total of 7 years of study participation.

Intervention

During the procedure you will be put to sleep under general anesthesia. Your study doctor will do a right heart catheterization to see how well or poorly your heart is pumping. In a right-heart catheterization, your study doctor guides a special catheter (a small, hollow tube), called a pulmonary artery (PA) catheter, into the right side of your heart. He or she then passes the tube into your pulmonary artery, this is the main artery that carries blood to your lungs. Your study doctor observes blood flow through your heart and measures the pressures inside your heart and lungs during the procedure. Your study doctor will then make the final determination to proceed with the AccuCinch device implantation.
You will have a Transesophageal Echocardiogram (TEE), which is a type of imaging where a long, thin tube is placed through your mouth and into your esophagus (*food tube*) to guide an ultrasound probe to see pictures of your heart. This is to help your study doctor see your heart, study catheters and the AccuCinch device during the implant procedure.
During the procedure, you will receive injections of dye and x-ray radiation so that the physician can determine the correct placement of the device. Your blood pressure will be monitored throughout the entire procedure through a tube in your blood vessel. Your study doctor may also give you antibiotics to reduce the chance of infection.
Your study doctor will insert the AccuCinch device through the main blood vessel in your groin and implant the device in your heart through a special catheter (a small hollow tube that is slightly smaller in diameter than a pencil). Your study doctor will place 10-16 small anchors underneath your mitral valve. A strong, thread-like cord will be threaded through these anchors and will be tightened to reduce the size of the pumping chamber of your heart.

Study burden and risks

POTENTIAL RISKS OF ROUTINE TESTS AND PROCEDURES

The potential risks associated with the screening and implant procedure may include, but are not limited to, the following:

• Allergic reaction to antithrombotic therapy (blood thinners), contrast medium (dye used for some x-ray procedures to allow visibility of structures inside your body), medication, or anesthesia
• Anemia (reduced number of red blood cells)
• Angina (chest pain)
• Aortic dissection (tearing of your primary blood vessel)
• Aortic valve thrombosis/occlusion (aortic valve becoming obstructed or blocked with a blood clot)
• Arrhythmias (irregular heartbeat) that may require you to undergo external electrical shocks
• Arteriovenous fistula (cross-mingling of blood between an artery and vein due to vessel damage)
• Bleeding or bruising
• Blood loss requiring blood transfusion
• Cardiac arrest (your heart stops beating, requiring chest compressions and/or shocks to re-start it)
• Cerebrovascular accident (including stroke or transient ischemic attack (TIA) in which there is sudden death of brain cells due to lack of blood flow to them with may cause symptoms of brain damage)
• Conduction disturbances (problem with the electrical system of your heart that makes your heartbeat and controls its rate and rhythm)
• Death
• Emboli (air, tissue, thrombotic) (air bubbles, small particles of tissue, or small blood clots released into the blood stream)
• Endocarditis (infection in your heart)
• Esophageal (food tube) irritation/pain, damage or rupture
• Gastrointestinal symptoms (having a stomachache or poor bowel function)
• Headache
• Heart failure
• Hematologic dyscrasia (a disorder of the blood cells)
• Hematoma (blood accumulation under the skin where it was cut or punctured)
• Hemolysis (damage to the red blood cells causing weakness, or tiredness and possibly requiring transfusion)
• Hemorrhage (a rapid loss of blood)
• Hypertension/Hypotension (high blood pressure/low blood pressure) requiring medication or device support
• Infection and/or pain at access site (where your skin was cut or punctured)
• Infection, fever
• Infection, systemic sepsis (infection of your whole body (sepsis)
• Intervention/conversion to open heart surgery
• Ionizing radiation risks
• Myocardial ischemia (blood flow to the heart is reduced, preventing the heart

muscle from receiving enough oxygen) or Heart Attack
• Perforation (a hole) or rupture of the heart structure
• Pericardial effusion/cardiac tamponade (fluid collection between the heart and the sac surrounding the heart)
• Pericarditis (an inflammation of the sac-like tissue that surrounds the heart)
• Peripheral ischemia (not enough blood supply to the arm or leg caused by narrowing or obstruction in the blood vessels).
• Peripheral (leg or arm) nerve injury/paralysis
• Pleural effusion (fluid collection in or around your lung or heart causing shortness of breath)
• Pneumonia (infection that inflames air sacs in one or both lungs)
• Pneumothorax (air enters the space between the lung and the chest wall)
• Postoperative encephalopathy (brain disease, damage or malfunction)
• Pseudoaneurysm (leakage of blood out of a blood vessel that is contained by surrounding tissue)
• Pulmonary edema (fluid build-up in your lungs)
• Renal insufficiency/failure (poor kidney function or worsening of kidney function)
• Respiratory insufficiency/failure (poor lung function or worsening of lung function)
• Shock, anaphylactic (life-threatening allergic reaction) or cardiogenic (poor pumping function of your heart)
• Thrombocytopenia (blood disorder)
• Vessel spasm
• Vessel thrombosis (blood clot formation)/occlusion (blockage)
• Vessel trauma requiring surgical repair or intervention
POTENTIAL RISKS OF ACCUCINCH SYSTEM

In addition to the potential risks listed above, the following risks associated with AccuCinch device include, but are not limited to:

• Allergic/immunologic reaction to the implant
• Aortic valve insufficiency (leaking of the valve between the main blood vessel that carries blood away from your heart to the rest of your body and the lower chamber of the left side of your heart)
• Aortic valve trauma
• Component embolization (any part of the device that that is released in the bloodstream and causes a sudden block in the blood vessel)
• Left ventricular outflow tract (LVOT) obstruction (a blockage of blood flow as blood is pumped from the main pumping chamber of the heart)
• Loss of therapy or benefit if the Cable breaks as the AccuCinch device becomes part of the wall of your heart
• Mitral valve apparatus damage (damage to the heart valve the separates the upper and lower chamber of the left side of your heart)
• Mitral valve stenosis (narrowing of the heart valve opening between the upper chamber to lower chamber of the left side of your heart)
• Worsening mitral regurgitation (leakage of blood from the lower chamber of

your heart to the upper chamber)

As with any research study, there is also the possibility of side effects not presently known. The study doctor and research staff will make every effort to minimize additional risks. As the research study progresses, you will be informed of any new study results that may affect your willingness to remain in the research study.

If you are female, you should not become pregnant or breastfeed a child while in this study. If you are sexually active and are able to become pregnant, you must use an acceptable form of birth control while you are in this study. Your study doctor will talk with you about the types of birth control that are acceptable to use while being in this study. Tell the study doctor right away if you become pregnant or think you are pregnant.

BENEFITS OF SCREENING TESTS AND/OR PROCEDURE
You may or may not receive any direct benefit from this research study.
SCREENING TESTS: The potential benefit from undergoing these screening assessments is that you will have undergone a thorough examination of your medical condition and you may have a better understanding of the available therapies for your condition.
PROCEDURE: If you are in the Device Group and the AccuCinch device has been implanted, you may experience an improvement in the symptoms related to your dilated heart. The study procedure techniques include a less invasive procedure than open-heart surgery, and it is anticipated that the study procedure will take less time and less anesthesia than an open-heart surgery. Treatment with the study device may provide both short and long-term relief of your symptoms, and an improvement of your cardiac function that could potentially increase both your life expectancy and improve your quality of life. It is possible that you will receive no direct benefit from this research study, but others may benefit in the future from the results of your participation.

Contacts

Public
Ancora Heart, Inc.

Burton Dr. 4001
Santa Clara CA 95054
US
Scientific
Ancora Heart, Inc.

Burton Dr. 4001
Santa Clara CA 95054
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age 18-years or older
2. Ejection Fraction: >=20 and <=40% measured by transthoracic echocardiography (TTE) and assessed by an echocardiography (echo) core lab
3. LV end-diastolic diameter >=55 mm measured by TTE and assessed by an echo core lab
4. Symptom Status:
a. NYHA III,
b. NYHA ambulatory IV, or
c. NYHA II with a heart failure hospitalizationa within the prior 12 months (of signing the consent)
5. Able to complete six-minute walk test with distance between 100 m and 450 m
6. Diagnosis and treatment for heart failure should be established at least 90 days before the date of consent
7. Prior to randomization, subjects should be on stable, optimally titrated medical therapy for at least 30 days, as recommended according to current guidelines as standard-of-care for Heart Failure therapy, with any intolerance documented
8. Able and willing to complete all qualifying diagnostic and functional tests, willing to accept blood product transfusion if required and agrees to comply with study follow-up schedule

Exclusion criteria

Cardiovascular
1. Myocardial infarction or any percutaneous cardiovascular intervention, cardiovascular surgery, or carotid surgery within 90 days prior to consent
2. Untreated clinically significant coronary artery disease (CAD) requiring revascularization
3. Computed tomographic (CT), fluoroscopic or echocardiographic evidence of severe aortic arch calcification, mobile aortic atheroma, intracardiac mass, thrombus or vegetation
4. Suboptimal ventricular anatomy or wall thickness as determined from screening echocardiography and/or CT scan
5. Heart failure on the basis other than ischemic or non-ischemic dilated cardiomyopathy (e.g., hypertrophic cardiomyopathy, amyloid cardiomyopathy, restrictive cardiomyopathy, uncorrected congenital heart disease, constrictive pericarditis)
6. Hemodynamic instability within 30 days prior to the implant defined as subject requiring inotropic support or mechanical hemodynamic support (e.g., left ventricular assist device (LVAD))
7. Any planned cardiac surgery or interventions within the next 180 days post-randomization (including therapeutic right heart procedures)
8. Active bacterial endocarditis
9. Severe RV dysfunction assessed by right heart catheterization (RHC) and/or TTE
10. Fixed pulmonary hypertension with PA systolic pressure >70 mmHg not responsive to vasodilator therapy
11. History of any stroke within the prior 90 days of consent or documented Modified Rankin Scale >= 2 disability from any prior stroke

Valvular
12. Mitral regurgitation grade 3+ (moderate-severe) or 4+ (severe)
13. Untreated degenerative (primary) mitral valve disease (mild prolapse with no need for intervention is allowable)
14. Prior mitral or aortic valve replacement
15. Tricuspid regurgitation grade 4+ (severe)
16. Moderate or severe aortic valve stenosis (AVA less than 1.5 cm2 or peak velocity AV Vmax >300 cm/sec)
17. Aortic regurgitation grade 2+ (moderate), 3+ (moderate-severe), or 4+ (severe)

Procedural
18. Anatomical pathology or constraints preventing appropriate access/implant of the AccuCinch Ventricular Restoration System (e.g., femoral arteries will not support a 20F Introducer sheath)
19. Renal insufficiency (i.e., eGFR of <25 ml/min/1.73 m2)
20. Subjects in whom anticoagulation during the procedure is contraindicated

21. Subjects in whom 90 days of antiplatelet therapy is contraindicated
22. Known allergy to nitinol, polyester, or polyethylene
23. 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 the index procedure

General
24. Life expectancy <1 year due to non-cardiac conditions
25. Currently participating in another interventional investigational study
26. Subjects on high dose steroids or high dose immunosuppressant therapy
27. Female subjects who are pregnant, of child-bearing potential without a documented birth control method, or who are lactating

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2023
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	AccuCinch® Ventricular Restoration System
Registration:	No

Ethics review

Approved WMO Date:	16-05-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-02-2025
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	NCT04331769
CCMO	NL83077.000.23