Percutaneous Ventricular Restoration in Chronic Heart Failure due to Ischemic Heart Disease

Published: 02-11-2011
Last updated: 27-04-2024

The primary objective is to assess the safety of the CardioKinetix Parachute Implant and Delivery System in the partitioning of the left ventricle inpatients with heart failure due to ischemic heart disease.

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

Summary

ID

NL-OMON36701

Source
ToetsingOnline

Brief title
PARACHUTE

Condition

- Heart failures

Synonym
apical aneurysm, chronic heart failure

Research involving
Human

Sponsors and support

Primary sponsor: CardioKinetix Inc.
Source(s) of monetary or material Support: Ministerie van OC&W,CardioKinetix, Inc.

Intervention

Keyword: parachute, Percutaneous, ventricular restoration

Outcome measures

Primary outcome

Assessment of safety defined as the successful delivery and deployment of the Parachute Implant through 6-month follow-up without the occurrence of Major Adverse Cardiac Events (MACE) related to the investigational device.

Secondary outcome

Change in Left Ventricular Volume Indexes (End Systolic {LVESVI} and End Diastolic {LVEDVI}) measured by echocardiography from baseline to 6 months.

Change in exercise tolerance from baseline to 6 and 12 month follow-up as measured by 6-Minute Walk Test.

Combined cardiovascular mortality and morbidity that includes all cause death, hospitalization for heart failure, myocardial infarction and stroke from baseline to 6, and 12 months.

Study description

Background summary

There are a number of treatment options available to minimize symptoms of heartfailure and somewhat slow disease progression. The combination of lifestyle changes and drug therapy*the foundation of almost all HF treatment regimens*can improve both survival rates and quality of life and is most often initiated in NYHA Class I and Class II patients. Each class of heart failure may warrant a different combination of medications. If drug therapy does not adequately enhance LV function, patients with advanced heart failure may become candidates for other interventions, including surgery and implantable devices.

While the above therapies may represent the best treatment available today for the majority of HF patients, the medical community recognizes that pharmacologic therapy has been optimized to nearly the extent that is possible, and that any incremental improvements in the management of HF patients will now come from device based therapies. With this background, a catheter-based treatment for patients with heart failure due to ischemic heart disease (left ventricular dilation after an anterior MI) has been developed. The implantable device, called the Parachute, is a partitioning membrane deployed within the compromised ventricle. The Parachute isolates the dysfunctional region of the ventricle and decreases chamber volume.The purpose of this study is to assess the safety of using the CardioKinetix Parachute device to isolate the malfunctioning portion of the left ventricle in patients with symptoms of HF due to ischemic heart disease.

Study objective

The primary objective is to assess the safety of the CardioKinetix Parachute Implant and Delivery System in the partitioning of the left ventricle in patients with heart failure due to ischemic heart disease.

Study design

The study is designed as a prospective, multi-center, non-randomized, dual arm, observational study of the CardioKinetix Parachute Implant and Delivery System.

Intervention

Percutaneous implantation of a Parachute in the left ventricle in patients with chronic heart faillure and due to ischemic heart dissease.

Study burden and risks

The risks associated with the implantation of the Parachute are expected not to be significantly different than cardiac catheterization and interventional procedures.

Clinical follow up at 6 months and 1,2,3,4 and 5 years post procedure. During the follow up at 6 and 12 months the patients will perform a 6 minute walk test and during the 6 month follow up there will be taken a chest X-ray.

The patients may benefit from participating in this study, because there may be improvement of hemodynamics and heart faillure symptoms after implantation of the Parachute.

Contacts

Public
CardioKinetix Inc.

925 Hamilton Ave
Menlo Park, CA 94025
US
Scientific
CardioKinetix Inc.

925 Hamilton Ave
Menlo Park, CA 94025
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Akinesis or dyskinesis due to previous myocardial infarction limited to anteroapical region.
Patient is not hospitalized at time of enrollment.
Diagnosis of heart failure for a minimum of 6 months prior to enrollment
NYHA Class III or IV .
Post LV myocardial infarction structural heart dysfunction represented by LV wall motion abnormality by echocardiography.
LVEF >15% and * 40% as measured by echocardiography.
Between 18 and 79 years of age.
Receiving appropriate medical treatment for heart failure.

Exclusion criteria

Untreated clinically significant coronary artery disease requiring intervention.
Acute myocardial infarction or revascularization procedure (PCI or CABG) within 60 days of enrollment.
Cardiogenic shock within 72 hours of enrollment.
Contraindication for asparin and anticoagulation therapy.
Moderate aortic stenosis and regurgitation >2+.
Aortic valve replacement or repair.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Parachute
Registration:	No

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL35125.018.11