

Observational study to collect data on health improvements after mini-invasive operation with Revivent TC device to reshape the heart and reduce its volume

Submission date 25/11/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/11/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A heart attack occurs when heart can no longer pump enough blood to meet the needs of the body. Since the circulating blood is not enough, the person experiences symptoms such as weakness, shortness of breath, fatigue (extreme tiredness) and fluid retention, which can cause swelling of the ankles or accumulation of fluid in the lungs. The most common cause of heart attack is the "ischemic cardiomyopathy", namely the block of one or more vessels that supply oxygen to the heart muscle. If the heart muscle is starved of oxygen, then parts of the muscle die and turn into hard scar tissue, which is not able to pump as well as the rest of the heart. The most effective treatment for this is to surgically remove the scarred tissue from the functioning heart muscle. Despite good results, this type of major heart surgery involves the patient being connected to a heart-lung machine, so that the heart can be stopped during surgery, which can be risky. This study is aiming to collect data on treatment outcomes achieved using the Revivent-TC system to perform this procedure: LIVE (Less Invasive Ventricular Enhancement, ventricular strengthening less invasive) that changes the size and shape of the heart without the use of a heart-lung machine and without the opening of the chest for surgery.

Who can participate?

Patients with heart failure symptoms who are receiving surgery using the Revivent-TC system to remove scar tissue from their heart.

What does the study involve?

The use of Revivent-TC system is carried out in accordance with normal clinical practice and does not require special procedures. Patients are followed-up for 5 years after their surgery to assess their medical condition. This involves undergoing a physical examination, a heart scan and an interview to find out if patients have experienced any side effects. These examinations take place 6 months, 1, 2, 3, 4 and 5 years after the procedure. At each visit, which can last up to an

hour depending patient's condition, the doctor asks patients about the type of medication they are taking, and to fill out a questionnaire about their general state of health, in the months after their last visit.

What are the possible benefits and risks of participating?

There is no guarantee or promise of benefit from participating in this study, because it consists only in gathering data for a treatment available on the market whose benefits have already been demonstrated. However, participation in the study will provide a means to closely monitor the health of each individual patient, with an immediate adjustment of therapy in cases where this is necessary. There are no particular risks associated with participation in this registry study because it provides the only collection of outpatient visits data of the non-invasive tests of routine that are not associated with health risks.

Where is the study run from?

1. Policlinico Sant'Orsola Malpighi and Policlinico Universitario Agostino Gemelli (Italy)
2. Asklepios Klinik St. Georg, CardioVascular Center (CVC) Frankfurt, University of Mainz Klinikum and St. Immanuel Klinikum Brandenburg (Germany)
3. University Hospital of Zürich (Switzerland)
4. NA Homolce Hospital (Czech Republic)

When is the study starting and how long is it expected to run for?

July 2016 to October 2022

Who is funding the study?

BioVentrix, Inc. (USA)

Who is the main contact?

1. Mr Noel Messenger (public)
2. Dr Monica Tocchi
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

CIP-0073

Study information

Scientific Title

BRAVE-TC: BioVentrix registry assessment of ventricular enhancement for the Revivent TC™ system

Acronym

BRAVE-TC

Study objectives

The aim of this study is to observe and record the results of the use of the Revivent TC Ventricular Enhancement System in a commercial, post-approval environment and to observe long-term safety and performance of the device over a 5-year follow-up period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Na Homolce Hospital, Prague EC, 05/10/2016, ref: 5.10.2016/25
2. Policlinico Agostino Gemelli EC, Rome, 15/09/2016, ref: Prot. N°32572/16
3. Kantonale Ethikkommission Zürich, 08/11/2016, ref: 2016-01321
4. Hessen Ethical Committee, 03/11/2016, ref: FF 106/2016

Study design

Multi-center prospective single-arm post-market registry

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Heart failure due to ischemic cardiomyopathy

Interventions

Participants receive ventricular reduction as part of their standard care. Prior to the operation, Cardiac Magnetic Resonance or Cardiac Tomography shall be used (according to institutional practice) to determine the extent of the area to treat and to qualify the patients for therapy. Ultra-sound examination (Transthoracic echocardiogram) shall be used to assess the size and shape of the heart before and after treatment. A 6-minute walking test shall be used to assess clinical status.

All adverse events are recorded prior to hospital discharge and at 30-days after treatment.

At 6 months, 1 year and annually for 5 years participants undergo the following assessments:

1. Physical examination
2. EKG
3. Cardiac imaging by Transthoracic Echocardiography according to institutional practice
4. Heart Failure Status (NYHA functional classification)
5. Quality of Life Assessment (Minnesota Living with Heart Failure Questionnaire, EuroQol-5D questionnaire)
6. 6-Minute Walk Test according to institutional practice
7. Data regarding any emergent treatment(s), heart failure related rehospitalization and/or adverse events

Intervention Type

Device

Primary outcome(s)

Decrease in Left Ventricular volume is measured using echocardiography at 6 months, 1, 2, 3, 4 and 5 years.

Key secondary outcome(s)

Changes in heart failure status assessed by Left Ventricular Ejection Fraction, New York Heart Association class, quality of life assessment, and walking distance as measured by a 6-minute walk exam at baseline, 6 months, 1, 2, 3, 4 and 5 years.

Completion date

19/10/2022

Eligibility

Key inclusion criteria

1. Patients suffering from heart failure symptoms with cardiac dysfunction caused by a previous myocardial infarction resulting in increased ventricular volume and anteroseptal or apical scar

Additional general inclusion criteria:

2. Subject is >18 years of age
3. Subject is able and willing to provide written informed consent
4. Subject is on guideline directed medical therapy (GDMT) for heart failure

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Inadequate myocardial viability in regions remote from the scar
2. Thrombus or intra-ventricular mass
3. Cardiac Resynchronization Therapy (CRT)
4. Patient intolerance or unwillingness to take anti-coagulation medication
5. Functioning pacemaker leads in antero-apical RV
6. Pulmonary Arterial Pressure > 60 mm Hg
7. Myocardial Infarction less than 90 days before the procedure
8. Previous right neck surgery, previous pericardiotomy, previous left chest surgery that precludes device placement
9. Chronic renal failure with a serum creatinine >2 mg/dL
10. Inoperable coronary disease with significant ischemia
11. Pulmonary disease that would preclude transient single lung ventilation

Date of first enrolment

19/10/2016

Date of final enrolment

01/01/2018

Locations

Countries of recruitment

Czech Republic

Germany

Italy

Switzerland

Study participating centre

Policlinico Sant'Orsola Malpighi

Via Pietro Albertoni, 15

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Study participating centre

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Study participating centre
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Sponsor information

Organisation
BioVentrix, Inc.

ROR
<https://ror.org/02yfz4y25>

Funder(s)

Funder type
Industry

Funder Name
BioVentrix, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

Data will be held by the manufacturer in the US, only in anonymous form. Not be made available because are applicable only for this technology and not for general purposes.

IPD sharing plan summary

Not expected to be made available