ISRCTN89757315 https://doi.org/10.1186/ISRCTN89757315

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

Registration date
29/11/2016

Overall study status
Completed

Last Edited
29/11/2016

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 due 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
medical@meditrialeurope.com

Contact information

Type(s)
Public

Contact name
Mr Noel Messenger

Contact details
12647 Alcosta Blvd.
Suite 400
San Ramon
United States of America
CA 94583

Type(s)
Scientific

Contact name
Dr Monica Tocchi

Contact details
Bösch 73
Hünenberg
Switzerland
CH-6331
+41 417 84 98 84
medical@meditrialeurope.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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.

Overall study start date
29/07/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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
Bologna
Italy
40138

Study participating centre
Asklepios Klinik St. Georg
Lohmühlenstr. 5
Hamburg
Germany
20099

Study participating centre
University Hospital of Zürich
Rämistrasse 100
Zurich
Switzerland
8091

Study participating centre
CardioVascular Center (CVC) Frankfurt
Seckbacher Landstraße 65
Frankfurt am Main
Germany
60389

Study participating centre
University of Mainz Klinikum
Langenbeckstraße 1

Mainz
Germany
55131

Study participating centre
Policlinico Universitario Agostino Gemelli
Largo Agostino Gemelli, 8
Rome
Italy
00168

Study participating centre
St. Immanuel Klinikum Brandenburg
Ladeburger Straße 17
Bernau
Germany
16321

Study participating centre
NA Homolce Hospital
Roentgenova 2
Prague
Czech Republic
150 30

Sponsor information

Organisation
BioVentrix, Inc.

Sponsor details
12647 Alcosta Blvd
Suite 400
San Ramon
United States of America
CA 94583

Sponsor type
Industry

ROR

https://ror.org/02yfz4y25

Funder(s)

Funder type
Industry

Funder Name
BioVentrix, Inc.

Results and Publications

Publication and dissemination plan
The sponsor and the investigators are committed to the publication and widespread dissemination of the results of the study. This study represents a joint effort between sponsors and investigators, and as such, the parties agree that the recommendation of any party concerning manuscripts or text shall be taken into consideration in the preparation of final scientific documents for publication or presentation. All proposed publications and presentations by the sponsor and investigators or their personnel and associates resulting from or relating to the study must be submitted to the Steering Committee for review and approval prior to submission for publication or presentation. If any such proposed publication or presentation contains patentable subject matter, which in the sponsor's opinion warrants intellectual proprietary protection, the sponsor may delay any publication or presentation for up to sixty (60) days after approval for the purpose of pursuing such protection. The number and order of authors shall be determined according to the rules of the addressed scientific journal.

Intention to publish date
28/02/2018

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