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Evaluation of cardiac dysfunction after transcatheter aortic valve replacement

Submission date
09/01/2017

Recruitment status
No longer recruiting

Registration date
12/01/2017

Overall study status
Completed

Last Edited
12/01/2017

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The healthy heart contains four valves, whose job it is to ensure that blood flows in the right direction through the heart. If one or more of these valves becomes damaged or diseased, then this can lead to narrowing of major blood vessels in the heart (cardiac stenosis) which block blood flow, which can increase risk of heart attack. Traditionally, the main surgical treatment was to perform major surgery, opening the chest and replacing the diseased valve with a new one. This procedure can be very dangerous however and some people are too unwell to have it performed on them. Transcatheter aortic valve replacement (TAVR) is a type of heart surgery which repairs damaged valves within the heart, without having to remove the old valves. Unlike many other types of heart surgery, this type of procedure does not require the chest being opened, as the procedure can be done through very small openings, such as through the femortal artery (large artery in the groin) or through a small incision (cut) in the chest. It is generally effective however data from a population of 380 patients from the University Hospital of Zurich recorded in the Swiss TAVR registry shows that some patients do not show improvement or can experience worsening of heart function after the procedure. This study is designed to evaluate the mechanisms of this phenomenon by measuring heart function during the TAVR treatment.

Who can participate?
Adults with severe cardiac stenosis who are suitable for TAVR.

What does the study involve?
After agreeing to take part, participants undergo a clinical examination to check that they are suitable to undergo treatment by TAVR. The surgical procedure is performed using standard techniques and involves the placing of an artificial valve in the heart by a thin tube (catheter) that enters the body through a small cut in the chest or through the main leg artery. During the treatment, heart function is assessed immediately before and after the valve is repaired by special tubes which measure how well the heart is working. Participants are followed up three months later with a range of heart scans to find out if heart function has improved.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, however the results of the study might help to

improve future patient management after TAVR. There are no notable risks other than the standard risks of complications when undergoing a TAVR.

Where is the study run from?
University Hospital of Zurich (Swizerland)

When is the study starting and how long is it expected to run for?
September 2016 to October 2017

Who is funding the study?
University Hospital of Zurich (Swizerland)

Who is the main contact?
1. Professor Francesco Maisano (scientific)
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2. Dr Andrea Guidotti (public)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIP-1601

Study information

Scientific Title
Prospective evaluation of afterload mismatch and myocardial contractile reserve in patients with ventricular dysfunction undergoing transcatheter aortic valve replacement

Acronym
REFIT

Study objectives
Perioperative pressure-volume loop recordings during TAVR will can help us to explain why about 50% of the patients with preoperative LVEF < 40% fail to improve their LVEF postoperatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee in Zurich, Switzerland

Study design
Single-centre non-randomised pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Aortic stenosis

Interventions
Pre-procedure, all patients will undergo TTE and Cardiac CT according to routine practice, to determine the indications for the procedure and compliance with the inclusion/exclusion criteria of the study. Individuals meeting inclusion criteria will be informed about the REFIT study and after giving their informed consent, their demographic characteristics and medical history will be recorded. Also all other standard examinations prior to TAVR will be performed, including physical examination, EuroScore assessment, clinical status, laboratory tests, medication recordings, ECG. Baseline TTE and cardiac CT will serve to plan the TAVR procedure. The procedure will consist of TAVR with pre- and post-procedural PV-loop recordings under echocardiographic and fluoroscopic guidance. At discharge, clinical status including medication, TEE, ECG and laboratory tests will be recorded as well as adverse events (AE) and documented in the CRF. Within the follow-up examination 3 months after the intervention, patients will be clinically examined and the same examinations will be repeated (TEE, ECG, laboratory testing). Medication and AE's will be recorded.

Intervention Type
Device

Primary outcome measure
Left ventricular contractility is measured by conductance catheters before and after TAVR.

Secondary outcome measures
1. Indexes of systolic function are derived by Transesophageal Echocardiography (TEE) before and after TAVR
2. Ventricular remodeling after the intervention is measured by comparing parameters derived from Transthoracic Echocardiography (TTE) at baseline and 3 months

Overall study start date
30/09/2017

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Informed Consent as documented by signature
2. Severe, symptomatic, calcific aortic stenosis who meet the commercially approved indications for TAVR
3. NYHA Functional Classification of II, III, or IV
4. Echocardiographic criteria: mean gradient >40 mmHg or jet velocity greater than 4.0 m/s and an initial aortic valve area (AVA) of < 0.8 cm2 (indexed EOA < 0.5 cm2/m2)
5. LVEF <40% as measured by resting echocardiogram
6. Patient is suitable for PV Loop procedure; no contraindication to Jugular vein and carotid artery cannulation
7. Aged 18-95 years

Participant type(s)
Patient

Age group
Senior

Lower age limit
18 Years

Upper age limit
95 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Any contraindication to TAVR procedure.
2. Low flow, low gradient aortic stenosis (LF/LGAS) (defined as an effective orifice area <1.0cm2 LV ejection fraction <40%, and mean pressure difference <30mmHg).
3. Hemodynamic instability at hospital admission, need for emergency surgery or intervention.
4. Bicuspid or unicuspid aortic valve
5. Other type of severe valve disease such as aortic regurgitation, mitral stenosis or mitral regurgitation
6. Pre-existing prosthetic heart valve or other implant in any valve position, prosthetic ring, severe mitral annular calcification (MAC), or severe (greater than 3+) mitral insufficiency.
7. Acute myocardial infarction (<30 days prior to procedure)
8. Atrial fibrillation
9. Life expectancy < 12 months
10. Vulnerable subjects / incapable of giving consent
11. Paravalvular Leak

Date of first enrolment
01/02/2017

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital of Zurich
Rämistrasse 100
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Sponsor information

Organisation
University of Zurich

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Zurich

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed Journal.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
For access to datasets, please contact Dr. Andrea Guidotti, University Hospital of Zurich, Zurich Switzerland; andrea.guidotti@usz.ch.

IPD sharing plan summary
Available on request