Transfemoral Replacement of Aortic Valve with HLT MeriDIAN Valve CE Mark Trial

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To evaluate the safety and performance of the HLT System in patients with symptomatic heart disease due to severe aortic stenosis who are judged by a Heart Team to be at Intermediate or High Risk for aortic valve replacement surgery

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON48296

Source
ToetsingOnline

Brief title
RADIANT CE MARK TRIAL

Condition

- Cardiac valve disorders

Synonym
severe aortic stenosis

Research involving
Human

Sponsors and support

Primary sponsor: HLT, Inc
Source(s) of monetary or material Support: sponsor HLT Inc

Intervention

Keyword: Aortic Valve, TAVR

Outcome measures

Primary outcome

The primary safety endpoint is all-cause mortality at 30 days

Secondary outcome

Secondary Performance Endpoint 1: Procedural Device Performance

The primary performance endpoint is Device Success defined as:

• Absence of procedural mortality AND

• Correct positioning of a single Valve into the proper anatomical location AND

• Intended performance of the Valve (no prosthesis-patient mismatch and mean aortic valve gradient < 20 mmHg or peak aortic valve velocity < 3 m/sec, AND no moderate or severe aortic valve regurgitation)

Secondary Performance Endpoint 2: Post-procedural Valve Performance

Valve performance will be evaluated by an independent Echo Core Laboratory at pre-discharge, 30 Days, 6, 12, 24, 36, 48 and 60 months for the following hemodynamic parameters:

• Aortic valve area (AVA)

• Aortic valve regurgitation (AR)

• Aortic valve gradient (Mean and Peak)

Secondary Safety Endpoint 3: Adverse Events

• All adverse events through the one (1) year follow up period

• All Serious Adverse Events through the five (5) year follow up period

• Major Adverse Cardiovascular and Cerebrovascular Events (MACCE) at 30 Days, 6

months, 12 months and annually through five (5) years

Study description

Background summary

Aortic valve stenosis is a common condition that is characterized by a reduced orifice opening and increased resistance to blood being pumped out of the left ventricle to the systemic circulation. It can result from rheumatic fever, congenital abnormalities (e.g. bicuspid valve) or from degenerative disease (senile, calcific) with progressive calcification. All three (3) causes result in fibrosis of the valve, thickening and fusion of the leaflets and restriction of valve opening. When stenosis becomes severe, it results in symptoms of angina, syncope and heart failure. In these patients, the mean time to death from onset of symptoms is five, three and two years, respectively (Banbury MK, 2002 May:73(5)).
Since there is no effective medical treatment, the current reference treatment for severe aortic stenosis is surgical aortic valve replacement (SAVR), which offers symptomatic relief and improved long-term survival in most patients. Standard SAVR includes using either a mechanical valve, or a bioprosthetic valve, made from animal tissue. Mechanical valves may have an infinite life, but the increased risk of stroke requires the concomitant use of anticoagulants, which increases the risk of bleeding. Tissue valves do not require the use of anticoagulants but are less durable than mechanical valves. Furthermore, SAVR requires a sternotomy and cardiopulmonary bypass and therefore can be associated with significant risk and morbidity (Lung B B. G., 2003 (24)). Surgical risk is higher in patients with left ventricular failure, concomitant coronary artery disease, chronic obstructive pulmonary disease (COPD) and advanced age. In addition, results from the Euro Heart survey suggest that up to 33% of patients with aortic stenosis were either not offered surgery because of high risk or declined surgery because of patient preference (Lung B e. a., 2005 Dec;26(24)).
see point 5.3 of the protocol

Study objective

To evaluate the safety and performance of the HLT System in patients with symptomatic heart disease due to severe aortic stenosis who are judged by a Heart Team to be at Intermediate or High Risk for aortic valve replacement

surgery

Study design

This is a prospective, non-randomized, single arm, multi-center CE Mark trial

Intervention

TAVR procedure

Study burden and risks

standard risks for TAVR and severe aortic valve stenosis

Contacts

Public
HLT, Inc

7351 Kirkwood Lane North, Suite 104
Maple Grove, MN 55369
US
Scientific
HLT, Inc

7351 Kirkwood Lane North, Suite 104
Maple Grove, MN 55369
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

1. Echocardiographic or hemodynamic based evidence of severe aortic stenosis with one of the following:
a) Aortic valve area <= 1.0 cm2 or 0.6 cm2/m2
b) Mean aortic valve gradient >= 40 mmHg
c) Peak aortic valve velocity >= 4 m/sec
2. Symptom*s due to severe aortic stenosis resulting in one of the following:
a) NYHA Functional Classification of II or greater
b) Presence of angina
c) Presence of syncope, 3. Documented aortic valve annular size of >= 24 and <= 26 mm (associated perimeter range is 76-81mm or associated area range of 453-530 mm2) by the MSCT Core Lab assessment of pre-procedure imaging. ,
4. Patient is considered intermediate or high risk to undergo surgical aortic valve replacement with one of the following:
a) Direct surgical risk STS-PROM score of >= 3% till 8%
b) great surgical risk STS-PROM score >=8%
C) Documented heart team agreement of risk for surgical aortic valve replacement (SAVR) due to other factors not captured by risk-scores (i.e. frailty or comorbidities)
5. Geographically available, willing to comply with follow up and able to provide written informed consent

Exclusion criteria

1. 1. Congenital unicuspid or bicuspid aortic valve, or noncalcified aortic valve; or valve eccentricity (calcific or otherwise) which could compromise procedural success , 3. Patients with low flow/low gradient aortic stenosis
4. Patients with significant annular or LVOT calcification that could compromise procedural success
5. Pre-existing prosthetic heart valve in any position, or prosthetic ring
7. Moderate to severe mitral stenosis
8. Myocardial infarction within the past 30 days*
10. Left Ventricular Ejection Fraction (LVEF) < 30%
22 Need for emergent surgery or intervention other than the investigational procedure
23 Any therapeutic invasive cardiac procedure performed or planned to perform within 30 days of the index procedure, except for PCI which is within 7 days of the index procedure

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-10-2019
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Meridian II AorticValve
Registration:	No

Ethics review

Approved WMO

Date:	21-02-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT03805711
CCMO	NL69163.078.19