The PULSTA(TM) Transcatheter Pulmonary Valve (TPV) Pre-Approval Study

Published: 19-08-2019
Last updated: 09-04-2024

The primary objective is to evaluate the safety and effectiveness of the PULSTA TPV System for the treatment of congenital or acquired heart disease with pulmonary valve disease and to gain data that will lead to CE mark approval for the PULSTA TPV...

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

Summary

ID

NL-OMON49198

Source
ToetsingOnline

Brief title
PULSTA TPV Study

Condition

- Cardiac valve disorders
- Cardiac and vascular disorders congenital

Synonym
pulmonary valve disease

Research involving
Human

Sponsors and support

Primary sponsor: Taewoong Medical Co., Ltd.
Source(s) of monetary or material Support: De sponsor (Taewoong Medical Co.;Ltd.)

Intervention

Keyword: heart disease, PULSTA TPV Study, stent, transcatheter pulmonary valve

Outcome measures

Primary outcome

1. Procedural / Device related-serious adverse events at 6 months

2. Hemodynamic functional improvement at 6 months

* Hemodynamic functional improvement is defined as mean RVOT gradient <=30 mmHg by continuous wave Doppler and a pulmonary regurgitant fraction <20% by cardiac MRI

Secondary outcome

Secondary Effectiveness endpoints are:

* Procedural success at discharge (Visit 3)

* Procedural success is defined as follows:

o If TPV is implanted on the desired site

o RV-PA peak systolic pressure gradient <35mmHg on cardiac catheterization

o If pulmonary regurgitation is < mild as assessed by angiography or echocardiography

o If TPV is not removed within 24 hours following implantation

* Hemodynamic function at all follow-up visits (Visits 3-10)

o Peak RVOT pressure gradient (by TTE)

o Mean RVOT pressure gradient (by TTE)

o RV end-diastolic volume index (RVEDV, by cardiac MRI at Visit 5)

* Pulmonary Regurgitant Fraction (PRF, by cardiac MRI at Visit 5)

* Severity of pulmonary regurgitation (Doppler echocardiography, Visit 1 and

Visit 3-10)

* NYHA functional classification (classification scale, Visit 1 and Visit 3-10)

Study description

Background summary

(Protocol section 1.)
Various congenital heart diseases, such as tetralogy of Fallot (TOF) involve a right ventricular outflow tract (RVOT) lesion, the treatment of which may lead to significant stenosis of the right ventricular outflow tract (=RVOT) or pulmonary regurgitation (insufficiency).

The treatment is either performed surgically replacing the pulmonary valve or transcutaneous using heart catherization. For artificial valves patients normally require anti-coagulation medication for life. For bioprosthetic valves no anti-coagulation medication is provided, however max. thrombocyte aggregation inhibition is required (e.g. Aspirin). These valves can degenerate over time resulting in multiple interventions.

Percutaneous implantation of pulmonary valves with the use of balloons (PPVI) does have restrictions, as the valve does not shape like the RVOT, but its shape is defined by the balloon. Especially in calcified RVOT this can create a risk of tearing. Also, the coronary arties running next to the RVOT may be compromised by the valve implantation.

The PULSTA Transcatheter Pulmonary Valve (TPV) System has been developed by Taewoong Medical Co., Ltd. and is a self-expandable valve with flared-ends to adapt to the larger native RVOT from knitted nitinol wire backbone(stent) and trileaflets made from treated porcine pericardial tissue. The device is using a relatively low profile delivery catheter.

Initial clinical results with the PULSTA TPV in patients with TOF demonstrated good short-term effectiveness without serious device related events (Kim et al., 2018). The current clinical investigation has been designed to meet the essential requirements of safety and performance for the PULSTA TPV System as intended for its CE marking in Europe.

Study objective

The primary objective is to evaluate the safety and effectiveness of the PULSTA

TPV System for the treatment of congenital or acquired heart disease with pulmonary valve disease and to gain data that will lead to CE mark approval for the PULSTA TPV System.

The secondary objectives are to evaluate the procedural success and hemodynamic function and safety of the PULSTA TPV System.

Study design

To support the CE marking of the PULSTA TPV System, the Sponsor will conduct a prospective, multinational, multicenter, non-randomization, open-label study to evaluate the safety and effectiveness of the PULSTA TPV implantation for the treatment of congenital or acquired heart disease with pulmonary valve disease.

All subjects included in the study and that fulfill the inclusion and exclusion criteria will receive the PULSTA TPV. No comparator valves or other treatments will be used in this clinical investigation. The device will not be explanted, other than if indicated or based on the investigator*s judgment. Subjects will be followed for 5 years.

Intervention

The PULSTAT(TM) Transcatheter Pulmonary Valve (TPV) System.

The PULSTA TPV is a self-expandable valve with flared-ends from knitted nitinol wire backbone to adapt to the larger native right ventricular outflow tract (RVOT) and valve leaflets made from treated porcine pericardial tissue, and a low-profile delivery system, which provides access to the right ventricular outflow tract through blood vessels.

Study burden and risks

Not applicable.

Contacts

Public
Taewoong Medical Co., Ltd.

Gojeong-ro, Wolgot-myeon 14
Gimpo-si 10022
KR
Scientific
Taewoong Medical Co., Ltd.

Gojeong-ro, Wolgot-myeon 14
Gimpo-si 10022
KR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Males and females aged >=16 years and weight >=30kg
2. Patients who are diagnosed with congenital or acquired heart disease with pulmonary valve disease and meet one or more of the following criteria:
- Moderate or severe pulmonary valve regurgitation as assessed by echocardiography
- Pulmonary valve stenosis with a mean gradient >35mmHg as assessed by echocardiography
3. Patients who have main pulmonary artery trunk of >=16 mm and <=30 mm
4. Patients whom are willing to participate in the study and willing to comply with the required treatments, procedures and attend all follow-up evaluations.
5. Patients who have been informed of the nature of the study, and have voluntarily provided written informed consent

Exclusion criteria

1. Females of child-bearing potential who are unable to take adequate contraceptive precautions, are known to be pregnant, or are currently breastfeeding an infant up until 6 months after TPV implantation
2. When patients have a mechanical valve implanted previously in pulmonary position or who require concomitant repair of other cardiac valves
3. When it is impossible to insert the delivery system since the central veins to be approached for the TPV implantation are obstructed

4. Patients who have coronary artery compression confirmed by angiography
5. Patients have known severe allergy to Nickel
6. Patients have a known hypersensitivity to any anticoagulation therapy, or a hemorrhagic disease
7. Patients have an immunocompromising disease such as malignant tumor or bone marrow transplant, or are immunosuppressed by chemotherapy, immunosuppressant, etc.
8. Patients have a known or suspected active infectious disease requiring antibiotic treatment such as meningitis, endocarditis, etc.
9. Patients have a known hypersensitivity to contrast agent or have severe renal insufficiency.
10.Patients with absolute or relative contraindications for MRI
11. Patients have less than 6 months of life expectancy according to the investigator*s clinical judgment
12. When patients have participated in a clinical study with other investigational drug or device within the past 3 months
13. When TPV implantation is impossible by the investigator*s judgment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2021
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	The PULSTA(TM) Transcatheter Pulmonary Valve (TPV) System
Registration:	No

Ethics review

Approved WMO Date:	19-08-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-05-2021
Application type:	Amendment
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	NCT03983512
CCMO	NL68549.078.19