Clinical Safety and Efficacy of the VDyne Transcatheter Tricuspid Valve Replacement System for the Treatment of Tricuspid Regurgitation VISTA

Published: 11-12-2024
Last updated: 19-04-2025

The purpose of this clinical study is to collect safety and efficacy data of the VDyne System to support Conformitè Europëenne (CE) Mark of the VDyne System.

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON57169

Source
ToetsingOnline

Brief title
VISTA Study TPR0038-P

Condition

- Heart failures

Synonym
a condition called Tricuspid Valve Regurgitation (TR); a condition caused by a leaky heart valve on the right side of the heart.

Research involving
Human

Sponsors and support

Primary sponsor: VDyne. Inc

Source(s) of monetary or material Support: Manufacturer of the device

Intervention

Keyword: heart failure, tricuspid valve regurgitation, valve replacement

Outcome measures

Primary outcome

The percentage of subjects with Device- and/or Procedure-related Major Adverse Events (MAEs) within 30 days of the procedure, as classified by the Clinical Events Committee (CEC).

MAEs consists of the following:

• Death (all cause, including cardiovascular and non-cardiovascular mortality)

• Myocardial Infarction (MI)

• Disabling Stroke

• Life-threatening bleeding (TVARC Bleeding Type 5 definition)

• Pulmonary embolism

• Renal failure requiring dialysis

• Need for additional surgical or interventional procedures (reintervention/re-operation) due to device deficiency

• Major access site and vascular complications

Stroke and bleeding classifications will be per TVARC. MI classifications will be per Valve Academic Research Consortium 3 (VARC-3).

The primary safety endpoint components will be analyzed and reported individually. The primary safety endpoint does not represent a composite endpoint.

Clinical Efficacy (measured at 30 days):

o Reduction in tricuspid valve regurgitation compared to baseline as

measured by the Imaging Core Labs

o Changes in symptom status (NYHA class)

o Changes in functional capacity (6-minute walk test) and

o Improvement in quality of life (KCCQ)

Secondary outcome

Safety: The percentage of subjects with Device- and/or Procedure related MAEs within 1 year post-procedure, as classified by the CEC. Mortality: The following mortality endpoints will be reported within 30 days postimplant: o All-cause mortality; o Cardiovascular mortality; o Non-cardiovascular mortality; o Procedural mortality (30 days from procedure or discharge from the hospital, whichever is longer); o Device related mortality Clinical Efficacy (measured at 3 months, 6 months and 1 year): o Reduction in tricuspid valve regurgitation compared to baseline as measured by the Imaging Core Labs o Changes in symptom status (NYHA class) o Changes in functional capacity (6-minute walk test) and o Improvement in quality of life (KCCQ) Intra-Procedural Success Intra-procedural success is defined below and will be evaluated upon exit from the procedure room: 1. Absence of procedural mortality or stroke; and 2. Successful access, delivery, and retrieval of the device delivery system; and 3. Successful deployment and correct positioning of the intended device(s) without requiring implantation of unplanned additional devices; and 4. Adequate performance of the transcatheter device. This includes the absence of tricuspid stenosis (TVA >1.5 cm2 or TVAi >0.9 cm2/m2 [>0.75 if BMI >30 kg/m2], DVI <2.2, mean gradient <5 mm Hg); reduction of total tricuspid regurgitation to optimal (1.5 cm2 or TVAi >0.9 cm2/m2 [>0.75 if BMI >30 kg/m2], DVI <2.2, mean gradient <5 mm Hg); reduction of total tricuspid regurgitation to optimal (1 functional class); and/or Improvement from baseline in functional status (e.g., 6-min walk test improvement by >50 m); and/or Improvement from baseline in quality-of-life (e.g., Kansas City Cardiomyopathy Questionnaire improvement by >5).

Study description

Background summary

Tricuspid valve regurgitation (TR) is estimated to impact 1.6 million people in the United States. Despite its high prevalence, TR is a largely untreated condition. and is known to be associated with poor life expectancy. Left uncorrected, moderate or greater secondary TR may progress is associated with higher heart failure hospitalization rates, increased morbidity and mortality,

and poor quality of life.

Study objective

The purpose of this clinical study is to collect safety and efficacy data of the VDyne System to support Conformitè Europëenne (CE) Mark of the VDyne System.

Study design

This study is a prospective, single-arm, multicenter, confirmatory, pre-market investigational study, to support conformity assessment and CE Mark of the VDyne System.

Intervention

The VDyne Valve is deployed by transfemoral implantation within the native tricuspid valve and is implanted under fluoroscopic and transesophageal echocardiography (TEE) guidance, while the heart remains beating, without the use of CPB. The valve is repositionable and fully retrievable intraoperatively.

Study burden and risks

The innovative VDyne System and side delivery approach represents a breakthrough technology where limited treatments currently exist for TTVR. Alternative therapies for TR currently include:
• Pharmaceutical treatment
• Open surgical valve repair techniques such as annuloplasty rings
• Open surgical valve replacement (mechanical or bioprosthetic valve)
• Transcatheter tricuspid valve repair (TTV Repair) techniques
• Transcatheter tricuspid valve replacement (TTVR)
The potential expected benefits of the VDyne System and procedure over available alternative therapies include:
• A safer procedure (e.g., potentially less time under general anesthesia, less blood loss, less morbidity, etc.) than open surgical valve repair or replacement due to the less invasive approach used to place the VDyne Valve. The VDyne procedure can be completed without the need for CPB, eliminating the risks and adverse consequences associated with open heartsurgery.
This may further decrease the risk of the procedure in patients who have advanced disease and thereby increased procedural risk.
• Preservation of the patient*s native tricuspid annulus, limiting interaction with surrounding anatomical features.
• The ability to reposition the VDyne Valve intraoperatively may also result in better performance as the VDyne Valve position within the native tricuspid annulus can be optimized intraoperatively.

• The ability to fully retrieve the VDyne Valve intraoperatively allows use of an alternative valve size or removal of the index VDyne Valve in the event of suboptimal valve delivery or other intraoperative complication.

The benefits that the VDyne System can give to patients suffering from TR are important, considering that the VDyne System can give opportunities for therapy to patients that are excluded for other surgical options. The overall risks associated with the use of the VDyne System are expected to be similar to risks associated with percutaneous transcatheter valve replacement and less than those compared to surgical valve repair or replacement due to the minimally invasive nature of the procedure. It is concluded that the likely benefits to patients, physicians, medical
science and society of the VDyne Transcatheter Tricuspid Valve Replacement System outweigh the potential risks.

Contacts

Public
VDyne. Inc

73rd Ave N Suite 116
Maple Grove 10900
US
Scientific
VDyne. Inc

73rd Ave N Suite 116
Maple Grove 10900
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Severe or greater tricuspid valve regurgitation of primary or secondary etiology.
2. NYHA class >= II. If NYHA Class IV, patient must be ambulatory.
3. Subject is adequately treated with medical therapy for heart failure > 30 days prior to index procedure, including a diuretic.
4. Heart Team determines patient is a recommended candidate for the VDyne System.
5. Age 18 years or older at time of the index procedure.
6. Clinical Screening Committee (CSC) and Imaging Core Labs confirm suitability for treatment with the VDyne System.

Exclusion criteria

VDYNE SYSTEM SUITABILITY
1. Patient anatomy (cardiac and vascular) is not suitable for the VDyne System as assessed by Imaging Core Labs, Sponsor and/or Clinical Screening Committee (CSC)
2. Intolerance to procedural anticoagulation or post-procedural antiplatelet/anticoagulation regimen that cannot be medically managed
3. Hypersensitivity to nickel or titanium
CLINICAL EXCLUSION CRITERIA (assessed by pre-procedural imaging)
4. Left Ventricular Ejection Fraction (LVEF) <30%
5. Severe RV dysfunction as assessed by the Clinical Screening Committee (CSC).
6. Significant abnormalities of the tricuspid valve and sub-valvular apparatus
7. Sepsis including active infective endocarditis (IE) (within the last 6 months)
8. Right ventricular, atrial thrombus, vegetation or mass on tricuspid valve.
9. Severe tricuspid annular or leaflets calcification
10. Systolic pulmonary hypertension with systolic pulmonary artery pressure >70 mmHg or pulmonary vascular resistance (PVR) >5 wood units as determined by RHC.
11. History of rheumatic fever that impacts the native tricuspid valve or surrounding structures.
CONCOMITANT PROCEDURES
12. Significant coronary artery disease requiring treatment such as symptomatic, unresolved multi-vessel or unprotected left main coronary artery disease
(CAD).
13. Any planned surgery or interventional procedure within 30 days prior to or following the implant procedure. This includes any planned concomitant cardiovascular procedure [e.g. Coronary Artery Bypass Grafting (CABG), percutaneous coronary intervention (PCI), pulmonary vein ablation, left atrial

appendage occlusion, septal defect repair, etc.]
14. Unresolved severe symptomatic carotid stenosis (> 70% by ultrasound)
15. Cardiac resynchronization therapy device or implantable pulse generator implanted within 60 days of planned implant procedure.
16. Permanent pacing leads that will interfere with delivery or implantation of the VDyne Valve.
17. Cardiogenic shock or hemodynamic instability requiring inotropes or mechanical support devices at the time of planned implant procedure.
18. Prior tricuspid valve surgery or catheter-based therapy with permanent residual device(s) implanted that would preclude delivery or implantation of the VDyne Valve (e.g. valve replacement, edge to edge repair, etc.)
19. Significant valvular heart disease requiring intervention other than the tricuspid valve
20. Known significant intracardiac shunt [e.g. septal defect), patent foramen ovales (PFOs) without significant shunts are allowed]
COMORBIDITIES
21. Cerebrovascular accident (stroke, TIA) within 6 months of treatment procedure
22. Severe lung disease [severe chronic obstructive pulmonary disease (COPD) or continuous use of home oxygen or oral steroids]
23. Acute myocardial infarction (AMI) within 30 days
24. Significant renal dysfunction (eGFR<30 ml/min/1.73m2) or on dialysis
25. End-stage liver disease (MELD > 11 and Child-Pugh class C)
26. Bleeding requiring transfusion within 30 days
27. Coagulopathy or other clotting disorder that cannot be medically managed
28. Chronic immunosuppression or other condition that could impair healing response
29. Any of the following: leukopenia, chronic anemia [Hemoglobin (Hgb) < 9], current thrombocytopenia (platelets <70), history of bleeding diathesis, or coagulopathy
30. Unwilling to receive blood products
GENERAL EXCLUSION CRITERIA
31. Known hypersensitivity or contraindication to procedural or post-procedural medications (e.g., contrast solution) which cannot be adequately managed medically
32. Life expectancy less than 12 months due to non-cardiac comorbidities
33. Treatment is not expected to provide benefit (futile)
34. Current IV Drug user (must be free drug abuse for > 1 year)
35. Pregnant, lactating or planning pregnancy during the course of the study
36. Vulnerable patient groups (minors, cognitively impaired persons, prisoners, persons whose willingness to volunteer could be unduly influenced by the expectation of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate, such as students, residents, and employees)
37. Currently participating in an investigational drug or device trial that has not reached its primary endpoint or is likely to interfere with this study
38. Patient (or legal guardian) unable or unwilling to provide written informed

consent before study-specific procedures are conducted
39. Patient unable or unwilling to comply with study required testing and followup visits.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-01-2025
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	VDyne Transcatheter Tricuspid Valve Replacement System
Registration:	No

Ethics review

Approved WMO Date:	11-12-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	02-04-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

(Nieuwegein)

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
Other	CIV-LT-21-04-036270
CCMO	NL87616.000.24