An Observational Real-world Study Evaluating Severe Tricuspid Regurgitation Patients Treated with the Abbott TriClipTM Device

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To confirm the safety and performance of the TriClip* Tricuspid Valve Repair System in a real-world setting.

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

Summary

ID

NL-OMON54878

Source
ToetsingOnline

Brief title
bRIGHT EU Post-Approval Study

Condition

- Cardiac valve disorders

Synonym
leakage of the heartvalve, Tricuspid regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: Heart Failure, Heart Valve, Tricuspid Regurgitation

Outcome measures

Primary outcome

The primary endpoint is Acute Procedural Success (APS) defined as successful implantation of the TriClip* device with resulting TR reduction at least 1 grade at discharge (30-day echocardiogram will be used if discharge is unavailable or uninterpretable). Subjects who die or undergo tricuspid valve surgery before discharge are considered to be an APS failure.

Secondary outcome

Secundary endpoint:

The secondary endpoint is a composite endpoint of all-cause mortality or tricuspid valve re-intervention/re-operation at 1 year.

Clinical Endpoints:

Assessed at discharge, 30-days, 1 year and annually through 5 years (unless indicated)

• Major Adverse Event (MAE) - MAE defined as a composite of cardiovascular mortality, myocardial infarction, stroke, new onset renal failure, endocarditis requiring surgery, and non-elective CV surgery for TriClip* device-related AE post-procedure

• Device Related Adverse Events (including Tricuspid valve stenosis, device embolization, Single Leaflet Device Attachment (SLDA), Myocardial perforation, or the need for Tricuspid valve replacement instead of repair due at least in

part to the TriClip* procedure or the presence of the TriClip* device)

• All-cause mortality

• TR grade, including change from baseline

• Number and duration of re-hospitalizations and reason for re-hospitalization

(i.e., heart failure, cardiovascular, non-cardiovascular)

• NYHA Functional Class improvement, Kansas City Cardiomyopathy questionnaire

• Composite of tricuspid valve re-intervention/re-operation or worsening of TR

• Composite of all-cause mortality or tricuspid valve

re-intervention/re-operation

Study description

Background summary

TR, or tricuspid valve insufficiency, is a failure of the tricuspid valve (TV) to close completely during systole resulting in leakage or *regurgitation* of blood from the right ventricle (RV) to the right atrium with each contraction of the RV. Symptoms associated with TR, are generally those of right-sided heart failure, include ascites, peripheral edema, hepatomegaly, decreased appetite, jugular vein enlargement and/or abdominal fullness. Additionally, TR severity is associated with worse survival regardless of LVEF or pulmonary artery pressure.TR has long been an overlooked condition.

Current treatment guidelines for TR indicate medical therapy to address venous congestion (e.g., diuretics) and/or treatment of the underlying disease to reduce TR (e.g., surgery)

The *Trial to Evaluate Treatment with Abbott Transcatheter Clip Repair System in Patients with Moderate or Greater Tricuspid Regurgitation (TRILUMINATE)* was initiated to investigate the safety and performance of the Tricuspid Valve Repair System (TVRS; also known as TriClip*). Six-month outcomes from the TRILUMINATE study were recently published in Lancet1. Both the primary safety and performance endpoints of the clinical study were successfully met. Tricuspid regurgitation (TR) was successfully reduced in 85.5% of the subjects who had available echocardiogram data and imaging at 30 day. At 6 months, only five (6.0%) subjects experienced a major adverse event (MAE). Furthermore,

subjects treated with the TriClip* device also experienced a significant improvement in quality of life and functional capacity1.
The TriClip* bRIGHT EU post-approval study (PAS) study is designed to confirm the safety and performance of the TriClip* device in a contemporary real-world setting.

Study objective

To confirm the safety and performance of the TriClip* Tricuspid Valve Repair System in a real-world setting.

Study design

The bRIGHT PAS study is a prospective, single arm, open-label, multi-center, post market registry, conducted to satisfy condition of CE Marking for the TriClip* TVRS.

Study burden and risks

The study follows the standard care and additional TTE's are made and blood withdrawals are performed specifically for the study. The additional risks are considered minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subjects (>=18 years age) have severe tricuspid regurgitation and are symptomatic despite
medical therapy.
2. Subjects eligible to receive the TriClip* per the current approved intended use and target patient
population.
3. Subject must provide written informed consent prior to study procedure.

Exclusion criteria

1. Subjects participating in another clinical study that may impact the follow-up or results of this
study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	01-03-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	TriClip System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-10-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-08-2024
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
ClinicalTrials.gov	NCT04483089
CCMO	NL74504.100.20