ARB-PMCF STUDY: ANNULOPLASTY RINGS & BAND POST-MARKET CLINICAL FOLLOW-UP STUDY

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The goal of the ARB-PMCF study is to evaluate the safety and performance of Abbott annuloplasty devices used in the surgical repair of mitral and tricuspid regurgitation for five years from implantation.The ARB-PMCF study aims to meet the EU Medical...

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

Summary

ID

NL-OMON51023

Source
ToetsingOnline

Brief title
ARB-PMCF

Condition

- Cardiac valve disorders

Synonym
heart failure, Heart valve disease

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: Annuloplasty device, Mitral valve, Surgical repair, Tricuspid valve

Outcome measures

Primary outcome

Safety (all groups):

Freedom from all-cause mortality at five years post-implant.

Performance (mitral groups, groups 1 and 2):

Freedom from surgical or transcatheter reintervention for mitral regurgitation

at five years post-implant.

Performance (tricuspid groups, groups 3 to 5):

Percent of subjects with at least a one-class improvement in NYHA functional

classification at one year.

Secondary outcome

• Freedom from the following events from implant through five years post

implant:

o All-cause mortality

o Cardiac death, as adjudicated by the CEC

o Operated valve related mortality, as adjudicated by the CEC

o Surgical reoperation on the repaired valve

o Transcatheter intervention on the repaired valve

o Reoperation or transcatheter intervention for regurgitation in the repaired

valve as adjudicated by the CEC

o The composite event of operated-valve endocarditis or thrombosis, thromboembolism, stroke, major bleeding or annuloplasty device dehiscence

o All-cause mortality and the composite event of operated-valve endocarditis or thrombosis, thromboembolism, stroke, major bleeding, or annuloplasty device dehiscence.

• NYHA Functional Class at baseline, discharge, and one, three and five years post-implant.

• Kidney and liver function lab test panel values at discharge, one, three and five years post-implant in Group 3 and 4 subjects.

• Cardiac medication usage at baseline, discharge, one, three and five years post-Implant.

• Transthoracic echocardiography (TTE) measurements of repaired valve regurgitation, repaired valve stenosis, ventricular remodeling and ventricular function at baseline, discharge, and one, three and five years post-implant.

Study description

Background summary

Valve disease is commonly classified as primary or secondary. Congenital or acquired primary disease directly alters or damages valvular tissue. The most prevalent primary mitral and tricuspid disease etiologies are degenerative and rheumatic,both of which are associated with annular dilation and remodeling. In secondary mitral and tricuspid disease, the deformation and dysfunction of otherwise normal valvular tissue is caused by diseases of the surrounding

cardiac anatomy, most commonly ischemic cardiomyopathy, left-sided valve disease, and arrhythmogenic atrial dilation. Enlargement of one or more heart chambers associated with these diseases can lead to mitral or tricuspid annular dilation and leaflet tethering that compromise leaflet coaptation. Primary disease is the most frequent indication for surgical mitral valve repair in the US, accounting for nearly three quarters of mitral repair surgeries. In recent, large (N >=180) tricuspid repair studies reporting on consecutive case series,however, secondary disease is the dominant surgical indication, accounting for roughly 90% of cases.

The most frequent consequence of mitral and tricuspid disease is valvular incompetence, where a failure of leaflet coaptation, or a torn or perforated leaflet, allows regurgitation through the closed valve into the atrium during systole. Moderate to severe mitral or tricuspid regurgitation are associated with markedly lower life expectancy. Prevalence estimates based on echocardiographic exam sampling in the US suggest moderate to severe mitral regurgitation (MR) is present in 2.0% of all adults and in 7.6% of adults aged 65 or older, while moderate to severe tricuspid regurgitation (TR) is present in 0.6% of all adults and 2.2% of those over age 65.

Mitral and tricuspid repair surgeries are accepted approaches to treatment of severe primary mitral or severe primary tricuspid disease. The difference in prognoses for these conditions with surgical repair as opposed to medical management alone is stark enough that the superior efficacy of surgical repair is considered self-evident, even in the absence of randomized controlled trials. When feasible, repair of primary mitral and tricuspid disease is preferred to valve replacement in US and European practice guidelines because the available evidence suggests repair offers both lower perioperative mortality and higher long-term survival.
Outcomes of secondary MR repair surgery are less favorable than primary MR repair outcomes. In the largest (N>200) surgical MR repair studies published in the past 15 years, reported five year survival after primary MR repair ranges from 82% to 99% with a sample-size-weighted mean of 93%, while after secondary MR repair the range is 52% to 85% with a sample-size-weighted mean of 71%. Two recent multicenter, randomized Cardiothoracic Surgery Network (CTSN) studies have provided further evidence of the limitations of secondary MR repair surgeries, with results suggesting that surgical replacement is preferable to surgical repair for severe secondary MR, and that the benefits of moderate MR repair in conjunction with CABG are doubtful.

There is no broad consensus or medical society guideline on annuloplasty device selection. Perioperative and long term survival, recurrence of regurgitation, and reoperation rates have been compared across annuloplasty device types (e.g., rigid vs. semi-rigid vs. flexible, partial vs. full) in a sizeable number of retrospective studies, a handful of small randomized trials and multiple systematic reviews and meta-analyses. Interpretation of these studies requires caution, given the abundance of potential confounding factors.

Annuloplasty is seldom performed in isolation and outcomes depend heavily on concomitant leaflet and/or subvalvular repairs and, in nearly all tricuspid repairs, on concomitant left sided valve repair or replacement. Even across otherwise identical surgeries with the same annuloplasty device, variation in surgeon sizing and/or suturing of the device can be the difference between an uncomplicated repair and one followed by excessive residual regurgitation, valvular stenosis, device dehiscence or mitral systolic anterior motion (SAM). Given these considerations and the lack of large, multicenter randomized trials comparing standardized surgical repair protocols, the reported differences in outcomes across annuloplasty devices have not been large enough or consistent enough to generate consensus guidance for use of particular annuloplasty device types for particular repair indications.

Study objective

The goal of the ARB-PMCF study is to evaluate the safety and performance of Abbott annuloplasty devices used in the surgical repair of mitral and tricuspid regurgitation for five years from implantation.

The ARB-PMCF study aims to meet the EU Medical Device Directives (MDD) requirements for clinical follow-up, post-marketing of the medical devices (PMCF).

The MDD requires equipment manufacturers to perform a PMCF study to confirm the clinical performance and safety over the expected lifespan of the medical device and acceptability of identified risks, and to detect emerging risks based on factual evidence.
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Study design

The ARB-PMCF Study has a multicenter, observational, parallel group design in which 550 subjects will be prospectively followed through five years after implant of an Abbott annuloplasty device in five treatment groups:

Group 1. Primary mitral disease repair (N=200) with the Rigid Saddle Ring, Séguin Ring or full Tailor Ring, without cut zone removal, including at least 50 implants of each ring model.
Group 2. Secondary mitral disease repair (N=200) with the Rigid Saddle Ring, Séguin Ring or full Tailor Ring, without cut zone removal, including at least 50 implants of each ring model.
Group 3. Primary tricuspid disease repair with the full Tailor Ring without cut zone removal (N=50).
Group 4. Secondary tricuspid disease repair with the full Tailor Ring without cut zone removal (N=50).
Group 5. Primary tricuspid disease repair with the Tailor Band or partial

Tailor Ring with the cut zone removed (N=50).

Study burden and risks

This investigation has an observational design in which nearly all data collected are from examinations, imaging, medical treatments and procedures that would have occurred in the absence of the investigation. In these instances, participation in the investigation poses no additional risk beyond what subjects would incur under the usual standard of care.

The investigation includes required TTE at the one-year, three-year and five-year visits which do not coincide with the usual standard of care. TTE has no known risks beyond the discomfort associated with having an ultrasound probe pressed against the skin of the chest and upper abdomen. Blood draws for hepatic and renal function panels are required for subjects in Groups 3 and 4. There are minor risks associated with collection of blood, including discomfort from the needle stick, a small risk of infection, bruising, swelling, bleeding or fainting. These risks are minimized by having a qualified person perform blood collection, adherence to aseptic technique and appropriate disinfection of the venipuncture site before needle insertion.

The burden for the subjects is that the one-year, three-year and five-year visits will have to be performed in the hospital and are not part of the standard of care. At the two-year and four-year visit there will be a phonecall with the researchteam, which is not part of the standard of care. Therefore the burden of participation consists of the additional time and additional procedures from the follow-up visits.

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. Subject is expected to undergo cardiac surgery in <=90 days including at least one of the
following:
a. implant of a Rigid Saddle Ring, Séguin Ring or a full Tailor Ring without cut zone removal
for mitral regurgitation (MR) repair
b. implant of a full Tailor Ring without cut zone removal for tricuspid regurgitation (TR) repair
c. implant of a Tailor Band for primary TR repair.
2. Subject*s cardiac surgery will be performed by a study investigator.
3. Subject will be at least 18 years age at the time of their annuloplasty device implant(s).
4. Subject provides written informed consent and agrees to comply with all required study visits
and procedures

Exclusion criteria

1. Subject is below the age of legal consent in the applicable jurisdiction or otherwise lacks legal
authority to provide informed consent.
2. Subject is unable to read or write or has a mental illness or disability that impairs their ability to
provide written informed consent.
3. Subject is expected to have or had active endocarditis at the time of their Abbott annuloplasty
device implant(s).

4. Subject cannot be unambiguously assigned to a treatment group due to missing data on repair
indication(s) or the model and configuration (cut zone removed or not) of their Abbott
annuloplasty implant(s).
5. Subject is participating in another clinical investigation including any treatment outside the
investigative site*s usual standard of care.
6. Subject has anomalous anatomy or medical, surgical, psychiatric or social history or conditions
that, in the investigator*s opinion, would limit the subject*s ability to participate in the clinical
investigation or to comply with follow-up requirements.

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):	07-07-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	SJM Rigid Saddle-ring;SJM Séguin Annuloplasty Ring;SJM Tailor Annuloplasty Ring;SJM Tailor Annulopla
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-03-2021
Application type:	First submission
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	NCT04761120
CCMO	NL76518.100.21