The SyncAV Post-Market Trial is a prospective, randomized, multi-center trial

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The SyncAV Post-Market Trial will evaluate changes in LV end-systolic volume (LVESV) between baseline (before CRT implant) and 12 months (post-randomization) in patients with CRT devices programmed with SyncAV compared to patients with CRT devices...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON54868

Source
ToetsingOnline

Brief title
SyncAV Post-Market Trial

Condition

- Heart failures

Synonym
Cardiac arrhythmias, Cardiac resynchronisation therapy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac resynchronisation therapy, Heart Failure, Sync AV algorithm

Outcome measures

Primary outcome

The primary endpoint of this trial will be evaluated at 12 months following trial randomization and is defined as the reduction of left ventricular end-systolic volume (LVESV) as a continuous variable from baseline to 12 months compared between subjects in the SyncAV and fixed AV delay arms.

Secondary outcome

One powered secondary endpoint will be evaluated at 12 months following trial randomization and is defined as:

• Percentage of subjects classified as CRT responders after 12 months of follow-up compared between subjects in the SyncAV and fixed AV delay arms, as measured by LVESV reduction of at least 15% compared to baseline. Subjects who died due to cardiovascular cause post randomization will be classified as non-responders.

Study description

Background summary

Cardiac resynchronization therapy (CRT) reduces mortality and hospitalizations for patients with heart failure, impaired LV function, and a wide QRS complex. Although the majority of patients benefit from CRT, approximately 30-40% of patients are classified as non-responders. The cause of non-response is multi-factorial and may be due in part to suboptimal LV lead placement and LV electrical activation.
CRT optimization to obtain ideal electrical resynchronization may improve response. This demands individualized device programming as changes in LV

function at different programmed settings can affect resynchronization. Numerous methods exist to achieve optimal CRT device programming, however, there is no consensus on the value of systematic optimization in all patients. Traditionally, clinicians have used echocardiography and/or invasive LV pressure to identify the best programming parameters, but both are costly, require exhaustive, iterative sampling, and often must occur in clinic or in a catherization laboratory. In addition, both optimization methods have failed in leading to improved clinical outcomes compared to nominal device settings. Electrocardiographic optimization is another widely used method to determine optimal CRT programming parameters. One specific method aims to fuse intrinsic conduction with RV and LV paced wave fronts with the goal of minimizing the QRS duration. Recent studies demonstrate that achieving these fusion optimized intervals results in superior clinical outcomes. Electrocardiographic optimization can also be accomplished through automatic, device-based algorithms utilizing intracardiac electrograms, which have obvious practical advantages compared to other methods. However, results from trials utilizing this technology have failed to demonstrate significant clinical improvement compared to more conventional optimization protocols. In the Smart-AV trial, AV optimization using a device-based algorithm did not lead to improved LV reverse remodeling compared to nominal device settings. Likewise, the Adaptive CRT trial showed that the device-based algorithm was non-inferior to echocardiographic optimization in CRT response based on the Clinical Composite Score (CCS).
These device-based algorithms may be limited due to their ability to only deliver a one-time, static, in-clinic CRT optimization, as this may not accommodate the daily range of cardiovascular conditions patients may exhibit. Truly effective optimization must frequently occur, if not continually, in all ambulatory conditions for CRT to fully adapt to the distinct cardiovascular dynamics of each patient.

Study objective

The SyncAV Post-Market Trial will evaluate changes in LV end-systolic volume (LVESV) between baseline (before CRT implant) and 12 months (post-randomization) in patients with CRT devices programmed with SyncAV compared to patients with CRT devices programmed with a fixed AV delay.

Study design

The SyncAV Post-Market Trial is a prospective, randomized, multi-center clinical trial designed to evaluate the impact of programming CRT devices using SyncAV on LV reverse remodeling compared with programming CRT devices using conventional CRT settings with a fixed AV delay.

Study burden and risks

No additional risk is associated with participation in the clinical trial. The burden will consist of filling out questionnaires at the follow up visits.
And for the subjects in the SyncAV group the extra time needed for optimization during the programming of the device.

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

Subjects must meet the following inclusion criteria for enrollment in the clinical trial.
1. Scheduled to receive a new CRT implant or an upgrade (Abbott CRT device and Abbott Quadripolar LV lead) from an existing implantable cardioverter defibrillator/pacemaker implant with no more than 10% RV pacing at the last device interrogation, no prior LV lead placement, AND meet the following

additional criteria:
a. Mild to severe heart failure despite optimal medical therapy for at least 3 months prior to signing consent. Optimal medical therapy is defined as maximal tolerated dose of beta-blockers and a therapeutic dose of angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, or aldosterone antagonist
b. LVEF <= 35% based on a prior standard of care echocardiogram
c. Left bundle branch block (LBBB) as documented on an ECG. Criteria for complete LBBB should include,
i. QRS duration >= 120 ms
ii. QS or rS pattern in leads V1
iii. mid-QRS notching or slurring in leads I, aVL, V5, and V6
iv. Absence of Q-wave in leads V5 and V6
d. Intact AV conduction (PR interval <= 280 ms on surface ECG)
2. At least 18 years old, or of legal age and willing and capable to give informed consent specific to each country and national laws
3. Willing and able to comply with the prescribed follow-up tests and schedule of evaluations

Exclusion criteria

Subjects will be excluded from enrollment if they meet any of the below exclusion criteria.
1. Recent myocardial infarction or unstable angina within 40 days prior to signing consent
2. Recent cardiac revascularization (angioplasty, stent or bypass graft) in the 4 weeks prior to signing consent or planned within 3 months following consent
3. Cerebrovascular accident or transient ischemic attack in the 3 months prior to signing consent
4. Any other therapeutic cardiovascular procedure (transcatheter aortic valve replacement, MitraClip, cardiac surgery, left atrial appendage closure, patent foramen ovale closure, or any ablation procedures) in the 3 months prior to signing consent
5. Permanent or persistent AF at the time of signing consent
6. Paroxysmal AF with at least one cardioversion within 60 days prior to signing consent
7. Prior CRT device implant
8. Prior His Bundle pacing implant or plan to have His Bundle pacing implant
9. Pregnant or breastfeeding at the time of signing consent
10. Incapacitated or unable to read or write
11. Undergone a cardiac transplantation or have a classification of Status 1 for cardiac transplantation or consideration for transplantation during the study follow-up period
12. Life expectancy < 12 months due to any condition
13. Unavailable for at least 12 months of follow-up visits

14. Enrolled in or intend to participate in a clinical drug and/or device study during this clinical trial which could confound the results of this trial as determined by Abbott

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2022
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Abbott CRT device;Abbott Quadripolar lead;RA and RV lead
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-06-2020
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-10-2021

Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL73054.099.20