# Non-invasive Electrocardiographic Imaging of SyncAV with MPP: Understanding Optimized Programming for Cardiac Resynchronization Therapy

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The objective of this clinical study is to evaluate the impact of Multipoint Pacing (MPP) and SyncAV programming on ventricular electrical activation time and activation sequence using noninvasive electrocardiographic imaging (ECGi) in patients...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Heart failures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54206

**Source**
ToetsingOnline

**Brief title**
ECGi of SyncAV with MPP

### 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, Electrocardiography, Heart Failure, SyncAV algorithm

## Outcome measures

### Primary outcome

The primary endpoint is acute reduction in the left ventricular activation time

(LVAT) and the standard deviation of activation times (SDAT) measured with ECGi

resulting from various CRT pacing configurations with MPP and SyncAV.

### Secondary outcome

Secondary endpoints are:

• Correlation between patient baseline characteristics, including LV size, and

LV electrical activation time during various CRT pacing

configurations with MPP and SyncAV.

• Correlation between traditional surface ECG-based QRS duration

narrowing and ECGi measured LVAT and SDAT reduction and relationship

to CRT device IEGM-based surrogates of activation.

• Relationship between scar location assessed with MRI and LV electrical

activation pattern during various CRT pacing configurations with

MPP and SyncAV.

• Acute reduction in the right ventricular activation time (RVAT) and the

mean and standard deviation of activation times (SDAT) measured with

ECGi resulting from various CRT pacing configurations with MPP and

SyncAV.

# Study description

**Background summary**

Cardiac resynchronization therapy (CRT) involves synchronous pacing from the right ventricle (RV) and left ventricle (LV) transvenously, typically via a lead placed in a lateral or postero-lateral coronary vein. There is considerable evidence demonstrating the value of CRT as a treatment for heart failure (HF) patients with prolonged QRS duration (QRSd). The clinical benefits of CRT include restoration of ventricular contractile coordination, reverse remodeling of the LV, reduced mortality rate, as well as improvement in LV systolic function, exercise tolerance, and quality of life. Additional improvement has been achieved with the introduction of MultiPoint* Pacing (MPP), whereby multiple LV sites along the single quadripolar lead are stimulated to capture a broader region of excitable myocardium.

Many programmable CRT and MPP parameters have been shown to have a significant impact on clinical outcomes. However, identifying the optimal set of parameters relies on an accurate assessment of relative cardiac function. Echocardiography and invasive LV pressure measurements have been considered the gold standard for direct, comprehensive hemodynamic optimization of CRT, but both are costly, time consuming, and must occur in clinic. In contrast, the surface electrograms (ECG) has been introduced as a simpler alternative, as the electrical synchrony restored by CRT is also registered in the QRS complex. Dyssynchrony is associated with a broad QRS complex, and vice versa. Accordingly, programming CRT with the goal of minimizing QRSd, specifically by achieving a fusion of paced and intrinsic beats, has resulted in superior clinical outcomes.

Conduction delays associated with the cardiac rhythm, and consequently QRSd, continuously adapt to an ever-changing cardiovascular status. Consequently, the timing of CRT stimuli must adapt accordingly to sustain optimal synchrony. An existing Abbott (ABT) feature, SyncAVTM, enables dynamic AV CRT timing adjustments in order to adapt to changes in intrinsic conduction, resulting in fusion pacing when properly optimized. If the AV node conduction down the RV is normal, SyncAV may be programmed to provide LV only pacing and resynchronize ventricular contraction in patients with left bundle branch block (LBBB).

Stimulation along a quadripolar lead results in heterogeneous LV activation, as shown by electrocardiography imaging (ECGi). Some preliminary work has indicated that MPP can improve hemodynamic response, as well as myocardium activation. Although it has been advocated that MPP captures more LV myocardium, resulting in faster depolarization, this has not been prospectively

examined and some studies indicate certain individual patients may worsen with MPP. The effectiveness of MPP could be influenced by local scar, heart size, morphology and LV lead position, among other factors.

Electrical optimization may play an important role in improving response to CRT. Attempts typically involve maximizing intrinsic LV electrical delay (qLV) at the site of pacing, narrowing the QRS, and minimizing LV paced activation time. Of these, minimizing LV paced activation duration has been shown to exhibit higher predictive value for CRT response compared to that of either qLV or QRS narrowing. As MPP is a pacing strategy, this may be an attractive tool to facilitate LV capture/activation and merits prospective analysis. In addition, preliminary results suggest that MPP programming may reduce LV-paced QRS duration beyond that of traditional LV bipolar pacing. However, LV-paced QRSd reflects biventricular activation and thus a more sensitive tool is required for this analysis to determine the effect of MPP on LV activation.

A small series utilizing endocardial contact mapping showed that the area of LV capture and rate of LV activation were impacted by MPP programming(17). Single beat whole chamber ECGi mapping may provide the strongest evidence of this effect. Further, the impact of the creation (or resolution) of lines of functional block with LV (or even RV) pacing is poorly understood. ECGi imaging facilitates identification of scar, line of block (functional or otherwise).

This clinical study is designed to evaluate the application of SyncAV and MPP to improve electrical synchrony and to determine the influencing factors on LV activation in patients receiving CRT using ECGi, which provides single beat, non-invasive cardiac mapping. The study will be a prospective, multicenter, single-arm interventional study recruiting approximately 50 patients.

## Study objective

The objective of this clinical study is to evaluate the impact of Multipoint Pacing (MPP) and SyncAV programming on ventricular electrical activation time and activation sequence using noninvasive electrocardiographic imaging (ECGi) in patients receiving cardiac resynchronization therapy (CRT).

## Study design

The ECGi with SyncAV with MPP study is a prospective, multicenter, single-arm interventional study designed to evaluate the application of SyncAV and MPP to improve electrical synchrony and to determine the influencing factors on LV activation in patients receiving CRT using ECGi which provides single beat, non-invasive cardiac mapping.

## Intervention

ECGi Data Collection Visit where device interrogation will be performed including:

• Pacing system information and parameters (impedance, sensing amplitudes, and programmed pacing settings)
• Record the intrinsic heart rate.
• Record device sensed AV conduction time (RAs-RVs).
• Record device paced AV conduction time (RAp-RVs).
• Using the Merlin programmer record the LV conduction times (RVs-LVs and RVp-LVs).
• Record qLV, qRV
• Record QuickOpt parameters

Electrical cardiac activation will be recorded from the ECGi system and with device IEGM recordings during various CRT pacing configurations.

**Study burden and risks**

The risks associated with the medical devices used in this clinical investigation can be found in the corresponding Instructions for Use (IFU). All devices are CE-marked and will be used in accordance with the approved indications and IFU. There are no additional risks introduced to study subjects.

There is no anticipated direct clinical benefit for patients participating in this study. However, it is possible that clinicians will gain information about the individual*s acute electrical response to a variety of pacing configurations. It is also possible the information learned could help add to the body of knowledge regarding acute response to changes in CRT programming and long term patient response.

The burden for the patient will be the ECG, NT-pro-BNP sample withdrawal, CT and ECGi which are not standard of care.
If baseline echocardiographic data were taken > 90 days from the scheduled baseline visit, the baseline echocardiographic data collection will have to be repeated, with the device off, prior to or on the day of the ECGi Data Collection Visit.

# Contacts

**Public**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Patients must meet ALL of the inclusion criteria to be considered for the clinical investigation.
1. Patients previously implanted with a SyncAV and MPP-enabled Abbott Quadripolar CRT
pacing system.
2. Patient must be > 18 years of age, able to provide informed consent and willing to comply with
study requirements
3. Sinus (or atrial paced) rhythm with intact AV conduction with PR interval <= 250 ms
4. Patient has documented Left Bundle Branch Block (LBBB)

## Exclusion criteria

Subjects will be excluded from enrollment if they meet any of the below exclusion criteria:
1. Resting heart rate > 100 bpm
2. AV Block (1st degree with PR> 250 ms, 2nd or 3rd degree)
3. Documented persistent atrial tachycardia or atrial fibrillation at the

moment of enrollment or
patients not likely to remain in sinus (or atrial paced) rhythm for the
duration of the study
4. Recent (< 3 months) myocardial infarction, ablation, electrolyte imbalance,
or any condition
within the last 90 days that would contraindicate for CRT programming
changes in the opinion
of the investigator
5. Women who are pregnant or plan to become pregnant during the study course

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 29-09-2021 |
| Enrollment: | 30 |
| Type: | Actual |

## Medical products/devices used

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

# Ethics review

Approved WMO

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| Date: | 17-03-2021 |
| Application type: | First submission |

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| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | NL74317.068.20 |

# Study results

Date completed: 12-07-2023

**Summary results**
Trial ended prematurely