Boston Scientific
Advancing science for life™

SYNCHRONICITY Study Design

Randomised, global trial of safety and effectiveness of left bundle branch area pacing vs conventional cardiac resynchronisation in HFrEF patients with LBBB.

For more than two decades, Boston Scientific has helped build the evidence base behind today's heart failure and CRT guidelines – from MADIT and MADIT II, through COMPANION, to MADIT-CRT. Building on this heritage, we are once again advancing the science of resynchronisation with SYNCHRONICITY: a randomised, global trial investigating left bundle branch area pacing (LBBAP) versus conventional CRT in HFrEF patients with LBBB.

Enrollment and follow-up

Total Subjects
Minimum of 850 randomisations at up to 100 sites

Visits
6 and 12 months, then annually thereafter (Follow-up to max 60 months)

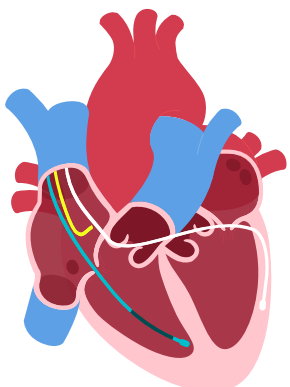
Qualified subjects will be **18 years or older** with left bundle branch block (LBBB) and a **guideline-based primary prevention indication** for a de novo **CRT-D** system.

Guideline directed medical therapy (**GDMT**) will be required for a minimum of 3 months prior to assessment of:

- **LVEF of ≤35%** within 6 months of enrolment
- **NYHA class II-IV** despite GDMT

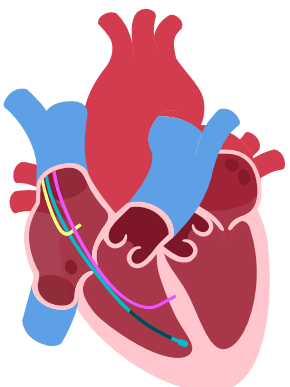
Subjects will be excluded if they have **persistent or permanent AF** (within 3 months of enrolment), prior or planned **tricuspid valve replacement**, frequent PVCs and **complete, second degree or high degree AV block.**

1:1 Randomisation



Conventional CRT-D
CS Lead +
RA Lead +
RV (Tachy) Lead

LBBAP CRT-D
LBBAP Lead +
RA Lead +
RV (Tachy) Lead



Clinical Endpoints

Primary Endpoints

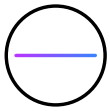
The primary endpoints will assess heart failure therapy for LBBAP compared to CRT therapy.

Primary Safety

- System-related complication-free rate (CFR) of LBBAP cohort at 12 months
- This endpoint will be compared to a performance goal

Primary Effectiveness

Composite of reduction in:



All-cause mortality

Heart transplant

Left ventricular assist device (LVAD)

Heart failure (HF) events

VT/VF requiring device therapy (ATP or shock) or external defibrillation/cardioversion

- This endpoint will be a comparison of LBBAP cohort to CRT cohort
- This endpoint analysis is to assess non-inferiority of LBBAP compared to CRT pacing

Secondary Endpoints

If the study passes the primary endpoints for non-inferiority, a series of secondary endpoints will be assessed for superiority conducted in the order below:

1. **Win Ratio (components shown below)**

Rank	Outcome
1	Death
2	Heart transplant/left ventricular assist device (LVAD) implant
3	Number of heart failure (HF) events
4	Number of VT/VF events requiring device therapy or external defibrillation/cardioversion (maximum of one episode per 24-hour period)
5	Change in MLHFQ Quality of Life

2. **Time-to-first composite endpoint (assessing for superiority)**
3. **System-related complications through 12-months, compared between the 2 cohorts**

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