More Options available with a quadripolar LV lead pRovidE in clinic solutions to CRT challenges

ClinicalTrials.gov identifier: NCT01510652

MORE-CRT Trial
Primary Results

ESC Congress 2014

Barcelona, Spain

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Disclosures: speaker fees from St Jude, Medtronic, Boston and Boehringer.

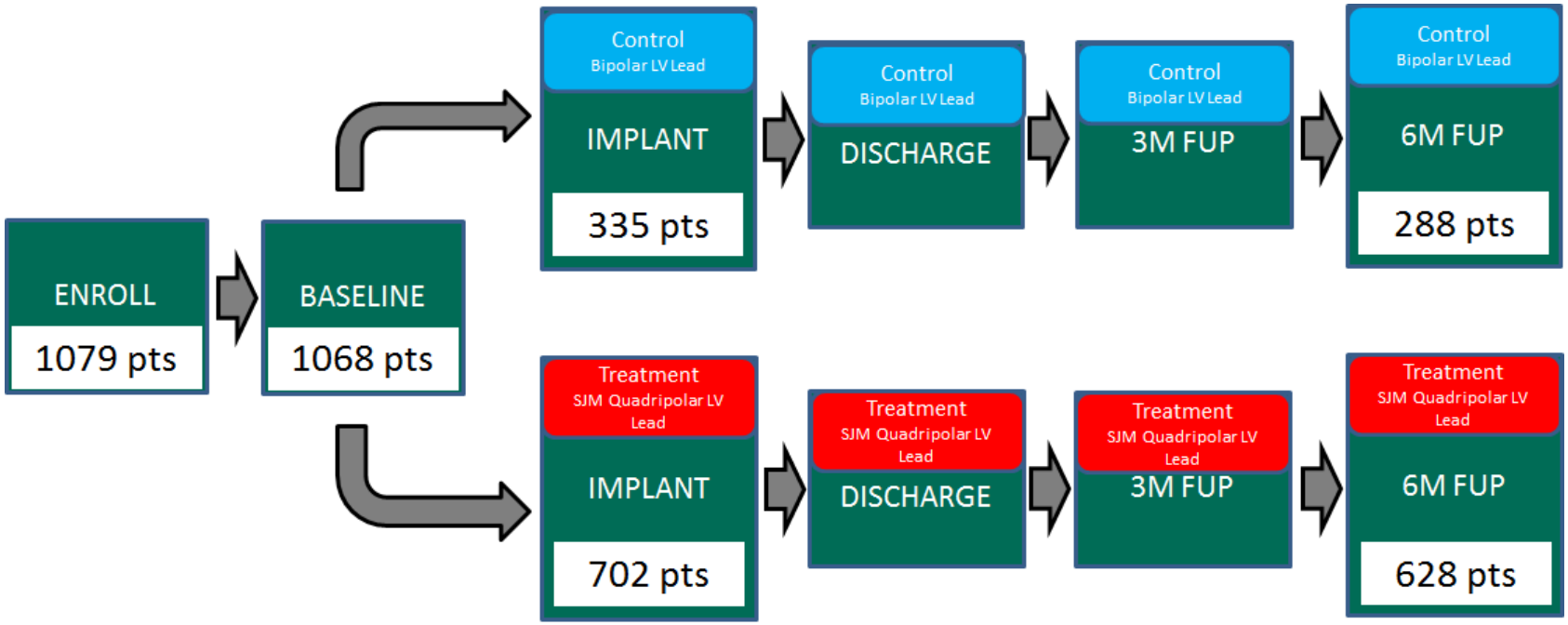
Trial sponsor:

ST. JUDE MEDICAL

Aim / Study Design

- AIM : To demonstrate that using the Quartet™ quadripolar left ventricular (LV) lead results in easier CRT implantation procedures and in a lower rate of lead related complications, as compared with currently used LV Bipolar leads

- Prospective, Open, Parallel, Multicenter Trial (approved by local IRB) Randomized (1:2 ratio) to St Jude Quartet™ 1458Q transvenous LV Lead vs. Bipolar (non-SJM /SJM) LV leads



Study Population

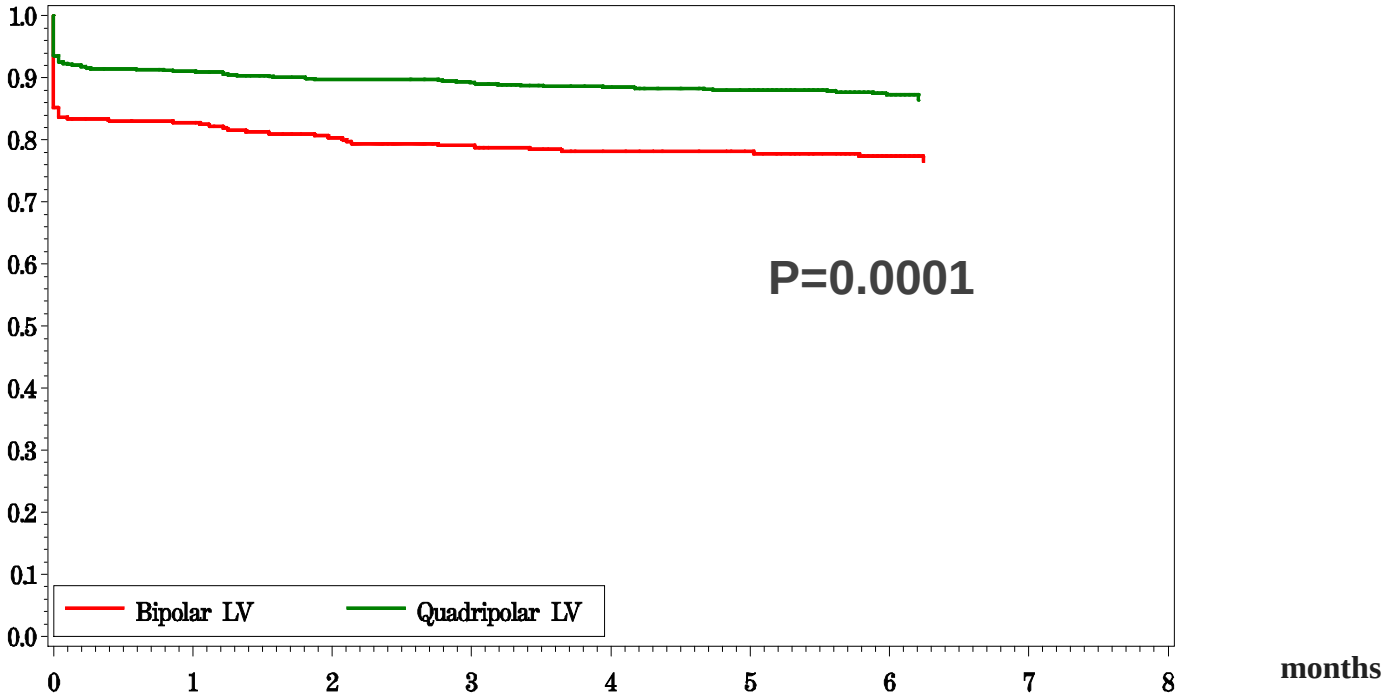
- 1079 pts Enrolled (101% of the Sample Size) in 13 Countries (63 centers) between November 2011 and August 2013
- 1068 pts contributed to Baseline data, randomized in 1:2 ratio:
  - **Control Group** (**Bipolar CRT System implant**): 348 pts
    - 1/3 SJM Bipolar LV leads
    - 2/3 non-SJM Bipolar LV leads (MDT, BSX, BTK, Sorin)
  - **Treatment Group** (**Quadripolar CRT system implant**): 720 pts
- 1053 pts contributed to the Primary Endpoint (combined)
  - 1037 pts contributed on the Intra-operative part of the endpoint
  - 1018 pts contributed on the Post operative part of the endpoint
- 916 pts reached the 6 months follow up visit

Primary Endpoint: Freedom from events

- Freedom from Combined Intra and Post-operative LV lead-related events

	Control	Treatment	P Value
Freedom from events %	76.86 %	85.97 %	0.0001

- Improvement in freedom from events by 11.85%



Primary Endpoint: Combined Event Rates

- Combined Intra and Post-operative LV lead-related Event Rates

	Total (n=1053)	**Control** (n=341)	**Treatment** (n=712)	**P Value**
Pt. Event Rate	16.14% (170)	22.29% (76)	13.20% (94)	0.0002

- Significant Relative Risk reduction (RR) by 40.8%
- Absolute Risk Reduction (ARR): 9
- Number Needed to Treat (NNT): 11

Results: Components of composite primary end-point = Intra-operative LV lead-related Events Rates

- Significant RR reduction in event rates by 56.4%
- ARR: 7.75
- NNT: 13

	Total (n=1037)	**Control** (n=335)	**Treatment** (n=702)	**P Value**
Intra Operative Events Rate	8.49% (88)	13.73% (46)	5.98% (42)	<0.0001

- Details:

	Total	**Control**	**Treatment**
Used more than 1 LV Lead	2.89%	6.48%	1.17%
Need to change vein	2.31%	3.46%	1.77%
Use of a device to fixate the lead	0.10%	0 %	0.15%
Unsuccessful Implant	3.95%	5.07%	3.42%

Conclusions

- In this large, prospective, randomized trial, the primary end point of freedom from intra-operative and post-operative lead-related events was significantly better in pts with quadripolar Quartet™ LV leads than those with any manufacturer Bipolar LV leads.
- The driver of benefit was a marked reduction in Intra-operative LV lead-related events (intra-operative complications rate was more than halved in comparison with bipolar leads)
- The performance and safety of SJM Quartet™ LV lead provide more options to effectively manage common pacing complications, as compared to systems based on Bipolar leads; hence, improving the efficiency of CRT.