7.13. Tables to Present

Table 1.1: Subject Disposition

	Site A	Site B	…	Total
Screened				
Randomised				
Arm A				
Arm B				
Withdrawn				
Reason for Withdrawal				
Completed				

Table 2.1: Number of protocol deviations by centre and category

Type of Deviation	**Site A**	**Site B**	**…**	**Total**
Patient was incorrectly included in the trial (did not meet all the inclusion and exclusion criteria				
⋮				
Patient pregnancy				
Other				
Total				

Table 3.1: Summary of Baseline Demographics

Variable	Statistics	Arm A [N=XX]	Arm B [N=XX]	All Subjects [N=XX]
Age (y)	n			
	Mean (SD)			
	Median (IQR)			
	Min, Max			
Ethnicity (%)	Asian			
	Black			
	Mixed			
	White			
Gender (%)	Female			
	Male			
Height (cm)	n			
	…			
Weight (kg)	n			
	…			
BMI	n			
	…			
Pulse	n			
	…			
Systolic BP	n			
	…			
Diastolic BP	n			
	…			

Table 4.1: Summary of MVO2 values by treatment and visit

Arm	Visit	Treatment	n	Mean	SD	Median	IQR	Min.	Max.
A	BL	-							
	M6	No-Pacing							
	M12	Pacing							
B	BL	-							
	M6	Pacing							
	M12	No-Pacing							

Table 4.2: Output of mixed-model test results for MVO2 by arm, treatment and timepoint

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Treatment				
Period				
Arm				
xxxx				
(Interaction Terms)				

Solution for Fixed Effects									
Effect	Treatment	Period	Arm	xxxx	Estimate	SE	DF	t Value	Pr > |t|
Intercept			-						
Treatment	…		-						
	…		-						
Period		…	-						
		…							
ARM	-	-	…	-					
	-	-	…	-					
xxxx				…					
(Interactions)	…	…							

Least Squares Means							
Effect	Estimate	Standard Error	DF	t Value	Pr > |t|	Adjustment	Adj P

Table 5.1.1: Summary of Echocardiographic Variables

Variable*	Arm	Visit	Treatment	n	Mean	SD	Median	IQR	Min.	Max.
	A	BL	-							
		M6	No-Pacing							
		M12	Pacing							
	B	BL	-							
		M6	Pacing							
		M12	No-Pacing							

***Variables to assess: LV end-diastolic diameter & volume, LV end-systolic diameter, LVEF and LVOT diameter.**

Table 5.1.2: Output of mixed-model for Echocardiographic Variables by arm, treatment and timepoint

Please refer to series of output in Table 4.2. Tests to be carried out on the following variables: LV end-diastolic diameter & volume, LV end-systolic diameter, LVEF and LVOT diameter.

Table 5.2.1: Summary of BNP Values

Arm	Visit	Treatment	Samples Taken	n	Mean	SD	Median	IQR	Min.	Max.
A	BL	-								
	M6	No-Pacing								
	M12	Pacing								
B	BL	-								
	M6	Pacing								
	M12	No-Pacing								

Table 5.2.2: Output of mixed-model for BNP by arm, treatment and timepoint

Please refer to series of output in Table 4.2.

Table 5.3.1: Summary of Quality of Life Scores

Variable*	Arm	Visit	Treatment	n	Mean	SD	Median	IQR	Min.	Max.
	A	BL	-							
		M6	No-Pacing							
		M12	Pacing							
	B	BL	-							
		M6	Pacing							
		M12	No-Pacing							

***Variables to assess: ED5Q5L and Minnesota Scores**

Table 5.3.2: Output of mixed-model for Quality of Life Scores by arm, treatment and timepoint

Please refer to series of output in Table 4.2. Variables to assess: ED5Q5L and Minnesota Scores

Table 5.4.1: Summary of Device Check Variables

Variable*	Arm	Visit	Treatment	n	Mean	SD	Median	IQR	Min.	Max.
	A	BL	-							
		M6	No-Pacing							
		M12	Pacing							
	B	BL	-							
		M6	Pacing							
		M12	No-Pacing							

***Variables to assess: %age HIS Paced, AF/SVT Burden, Impedance of RA, His & LV/ICD Leads, Pacing Thresholds of RA, His & LV/ICD Leads, P-Wave Amplitude, Total Fluoroscopy Time**

Table 5.4.2: Output of mixed-model for Device Check Variables by arm, treatment and timepoint

Please refer to series of output in Table 4.2. Variables to assess: %age HIS Paced, AF/SVT Burden. Remaining variables are to be summarised only.

Table 5.5.1: Summary of Exercise Time values

Variable*	Arm	Visit	Treatment	n	Mean	SD	Median	IQR	Min.	Max.
	A	BL	-							
		M6	No-Pacing							
		M12	Pacing							
	B	BL	-							
		M6	Pacing							
		M12	No-Pacing							

Table 5.5.2: Output of mixed-model for Exercise Time values by arm, treatment and timepoint

Please refer to series of output in Table 4.2.

Table 5.6.1: Summary of Haemodynamic Response values

Variable*	Arm	Visit	Treatment	n	Mean	SD	Median	IQR	Min.	Max.
	A	BL	-							
		M6	No-Pacing							
		M12	Pacing							
	B	BL	-							
		M6	Pacing							
		M12	No-Pacing							

Table 5.6.2: Output of mixed-model for Haemodynamic Response values by arm, treatment and timepoint

Please refer to series of output in Table 4.2.

Sub-Group Analysis Output

Table 6.1.1 –6.1.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for QRS Category

Please refer to output within Table 4.2

Table 6.1.4 –6.1.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for QRS Category dichotomised as Narrow QRS vs Non-Narrow QRS

Please refer to output within Table 4.2

Table 6.2.1 –6.2.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for PR Interval at Implantation (as continuous variable)

Please refer to output within Table 4.2

Table 6.2.4 –6.2.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for PR Interval at Implantation (as tertile groups)

Please refer to output within Table 4.2

Table 6.3.1- 6.3.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients grouped by E-A fusion

Please refer to output within Table 4.2

Table 6.4.1 –6.4.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for selective vs non-selective His capture

Please refer to output within Table 4.2

Table 6.5.1 –6.5.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients based on lead implantation (LV Lead vs His Lead)

Please refer to output within Table 4.2

Table 6.6.1 –6.6.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients dichotomised by Ejection Fraction

Please refer to output within Table 4.2

Table 6.7.1 –6.7.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients dichotomised by Device Type

Please refer to output within Table 4.2

Table 6.8.1 –6.8.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients BMI (as continuous variable)

Please refer to output within Table 4.2

Table 6.8.4 –6.8.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients BMI (as tertile groups)

Please refer to output within Table 4.2

Table 6.9.1 –6.9.3 - Output of mixed-model for MVO2 by arm, treatment and timepoint including sub-group variable for patients Max RER Value (as continuous variable)

Please refer to output within Table 4.2

Table 6.9.4 –6.9.6 - Output of mixed-model for MVO2 by arm, treatment and timepoint including sub-group variable for patients dichotomised by

Please refer to output within Table 4.2

Table 6.10.1 –6.10.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients height (as continuous variable)

Please refer to output within Table 4.2

Table 6.10.4 –6.10.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for patients height (as tertile groups)

Please refer to output within Table 4.2

Table 6.11.1 –6.11.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for percentage-His pacing (as continuous variable)

Please refer to output within Table 4.2

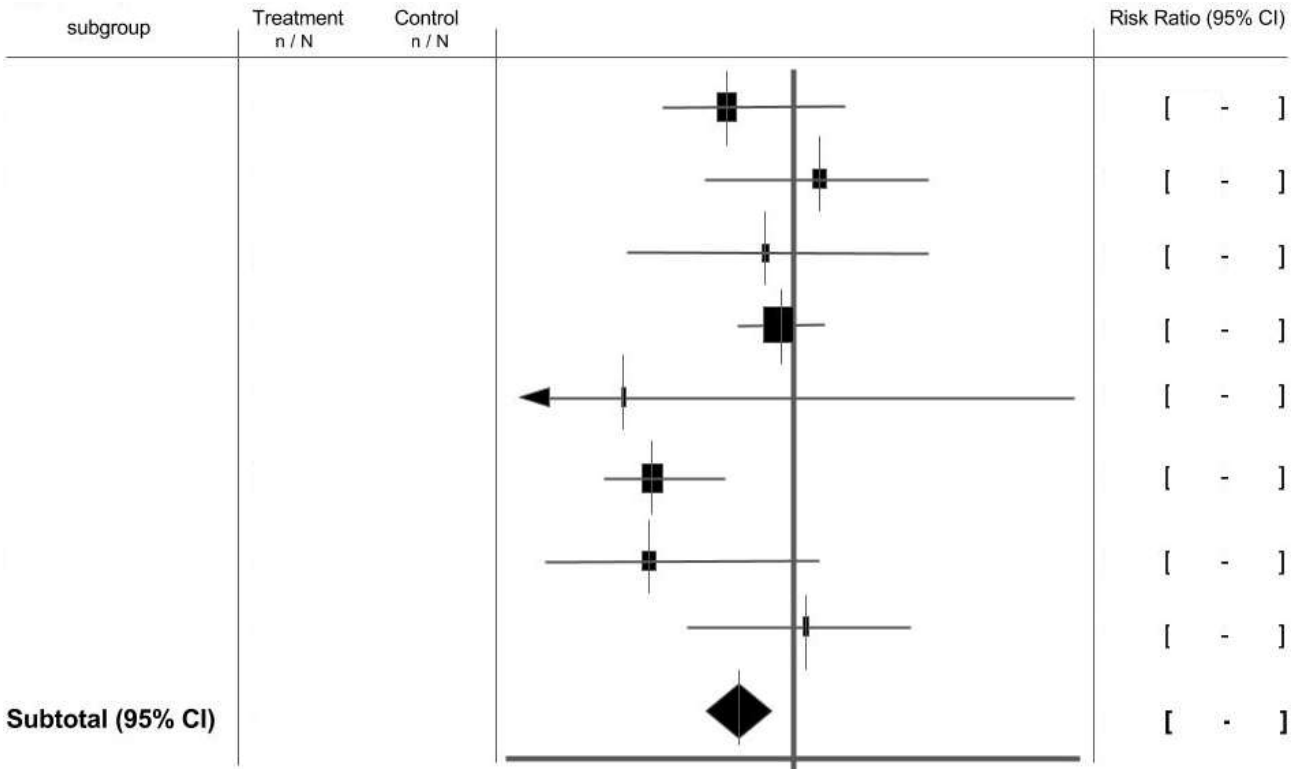
Table 6.11.4 –6.11.6 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for percentage-His pacing (dichotomised) as ≤ 95% vs > 95%

Please refer to output within Table 4.2

Table 6.12.1 –6.12.3 - Output of mixed-model for MVO2/Daily Activity/Haemodynamic Response by arm, treatment and timepoint including sub-group variable for His-Pacing adherence (as binomial variable)

Please refer to output within Table 4.2

Table 6.11.1 –6.11.3: Forest Plot of Sub-Group Analysis for MVO2/Daily Activity/Haemodynamic Response *



***To include:**

- **QRS Morphology (Dichotomised as Narrow QRS Duration/Non-Narrow QRS)**
- **PR Interval (Tertiles –Low vs Medium and Low vs High)**
- **Baseline Echocardiography (E/A Fusion)**
- **Selective vs Non-Selective His Bundle Pacing**
- **LV Lead vs His Lead**
- **Ejection Fraction Group (dichotomised as ≤35**
- **Device Type (Dichotomised as ICD vs non-ICD)**
- **BMI (Tertiles –Low vs Medium and Low vs High)**
- **Max RER Score (Tertiles - <0.95 vs 0.95-1.05, <0.95 vs >1.05)**
- **Height (Tertiles –Low vs Medium and Low vs High)**
- **Percentage His-pacing (dichotomised as ≤95% vs >95%)**
- **Adherence to optimal pacing based on metrics obtained at V4/V5 and AE data (binary)**

Safety Analysis Output

Table 7.1.1: Summary of Adverse Events by Treatment, Arm and Severity

		Pacing			No-Pacing		
		Arm 1	Arm 2	Total	Arm 1	Arm 2	Total
Severity	Mild						
	Moderate						
	Severe						
	Total						

Table 7.1.2: Summary of Adverse Events by Treatment, Arm and Relationship to Study

		Subjects with AEs*						
Treatment	Arm	No Relationship	Unlikely	Possible	Probable	Definitely	Not Yet Defined	Total
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								

		All AEs						
Treatment	Arm	No Relationship	Unlikely	Possible	Probable	Definitely	Not Yet Defined	Total
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								

* For subjects with ranking AE will be used. AE's the highest

Table 7.2.1: Summary of Adverse Device Effects by Treatment, Arm and Severity

		Pacing			No-Pacing		
		Arm 1	Arm 2	Total	Arm 1	Arm 2	Total
Severity	Mild						
	Moderate						
	Severe						
	Total						

Table 7.2.2: Summary of Adverse Device Effects by Treatment, Arm and Relationship to Study

		Subjects with AEs*						
Treatment	**Arm**	**No Relationship**	**Unlikely**	**Possible**	**Probable**	**Definitely**	**Not Yet Defined**	**Total**
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								
		All AEs						
Treatment	**Arm**	**No Relationship**	**Unlikely**	**Possible**	**Probable**	**Definitely**	**Not Yet Defined**	**Total**
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								

*** For subjects with ranking AE will be used. AE's the highest**

Table 7.3.1: Summary of Serious Adverse Events by Treatment, Arm and Severity

		Pacing			No-Pacing		
		Arm 1	Arm 2	Total	Arm 1	Arm 2	Total
Severity	Mild						
	Moderate						
	Severe						
	Total						

Table 7.3.2: Summary of Serious Adverse Events by Treatment, Arm and Relationship to Study

		Subjects with SAEs*						
Treatment	Arm	No Relationship	Unlikely	Possible	Probable	Definitely	Not Yet Defined	Total
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								

		All SAEs						
Treatment	Arm	No Relationship	Unlikely	Possible	Probable	Definitely	Not Yet Defined	Total
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								

* For subjects with ranking AE will be used. AE's the highest

Table 7.4.1: Summary of Serious Adverse Device Effects by Treatment, Arm and Severity

		Pacing			No-Pacing		
		Arm 1	Arm 2	Total	Arm 1	Arm 2	Total
Severity	Mild						
	Moderate						
	Severe						
	Total						

Table 7.4.3: Summary of Serious Adverse Device Effects by Treatment, Arm and Relationship to Study

		Subjects with SAEs*						
Treatment	**Arm**	**No Relationship**	**Unlikely**	**Possible**	**Probable**	**Definitely**	**Not Yet Defined**	**Total**
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								
		All SAEs						
Treatment	**Arm**	**No Relationship**	**Unlikely**	**Possible**	**Probable**	**Definitely**	**Not Yet Defined**	**Total**
Pacing	1							
	2							
	Both							
No-pacing	1							
	2							
	Both							
All subjects								

*** For subjects with ranking AE will be used. AE's the highest**

Table 7.5.1 –7.5.4: Mixed Effect Logistic Regression output to investigate proportional rate occurrence for Rates of Death/Hospitalisation/Revision of Device/Extraction or Removal of Device by treatment, period and sequence

Please refer to series of output in Table 4.2.

Table 7.6.1: Summary of Vital Signs Values

Variable*	Arm	Visit	Treatment	Samples Taken	n	Mean	SD	Median	Min.	Max.
	A	BL	-							
		M6	Control							
		M12	Treatment							
	B	BL	-							
		M6	Treatment							
		M12	Control							

***Variables to assess: Height, weight, pulse, BMI, Dia/Sys Blood Pressure Average**

Appendix A - Listings

Listing A: Listing of MVO2 values

Treatment	Subject	Site	Type	Start Date	End Date

Listing B: Listing of protocol deviations

Treatment	Subject	Site	Type	Start Date	End Date

Listing C: Listing of protocol violations

Treatment	Subject	Site	Type	Start Date	End Date

Listing D: Listing of Serious Adverse Events

Treatment: Pacing

Timepoint	Subj	AE Term	SAE Start Date	Ongoing	SAE End Date	Days frm Implant	Days frm Rand.	SAE Category	Expected-ness	Rel. to Study	Details

Treatment: No-Pacing

Timepoint	Subj	AE Term	SAE Start Date	Ongoing	SAE End Date	Days frm Implant	Days frm Rand.	SAE Category	Expected-ness	Rel. to Study	Details

Listing E: Listing of Serious Adverse Device Effects

Treatment: Pacing

Timepoint	Subj	AE Term	SAE Start Date	Ongoing	SAE End Date	Days frm Implant	Days frm Rand.	SAE Category	Expected-ness	Rel. to Device	Details

Treatment: No-Pacing

Timepoint	Subj	AE Term	SAE Start Date	Ongoing	SAE End Date	Days frm Implant	Days frm Rand.	SAE Category	Expected-ness	Rel. to Device	Details

REFERENCES

HOPE-HF Study Protocol v6.0 25Jan2018