Statistical Analysis Cover Page

Study Title: Nicotinamide Riboside in LVAD Recipients (PilotNR-LVAD)

NCT Number Document Description Document Date

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Statistical Analysis Template — *ClinicalTrials.gov*

Statistical Analysis Overview	* Comparison Group Selection ①	☒ Arm/Group 1 ☐ Arm/Group 2 ☐ Arm/Group 3
	Comments ②	We performed a Pre- and Post-NR intervention comparison
	* Type of Statistical Test	**(Select One)** Superiority; Equivalence; Non-inferiority; ○ Other (for example, single group or other descriptive analysis)
	[*] Comments ③	
Statistical Test of Hypothesis	**[*]** P-Value (if applicable)	0.0405 *(calculated value, not the a priori threshold for statistical significance)*
	Comments ②	We performed a pairwise 2-tailed student's T-test to compare the Pre-NR and Post-NR PBMC Maximal Respiration
	[*] Method (required if p-value entered)	**(Select One)** ANCOVA; ANOVA; Chi-Squared; Chi-Squared, Corrected; Cochran-Mantel-Haenszel; Fisher Exact; Kruskal-Wallis; Log Rank; Mantel Haenszel; McNemar; Mixed Models Analysis; Regression, Cox; Regression, Linear; Regression, Logistic; Sign Test; ○ t-Test, 1-Sided; t-Test, 2-Sided; Wilcoxon (Mann-Whitney); Other (_____)
	Comments ②	
Method of Estimation	**[*]** Estimation Parameter (if applicable)	**(Select One)** Cox Proportional Hazard; Hazard Ratio (HR); Hazard Ratio, Log; Mean Difference (Final Values); ○ Mean Difference (Net); Median Difference (Final Values); Median Difference (Net); Odds Ratio (OR); Odds Ratio, Log; Risk Difference (RD); Risk Ratio (RR); Risk Ratio, Log; Slope; Other (_____)
	Estimated Value	_____ *(calculated value)*
	Confidence Interval (if applicable)	**Level:** _____ % Confidence Interval **Number of Sides: (Select One)** 2-sided 1-sided **Lower Limit:** _____ **Upper Limit:** _____
	Parameter Dispersion	**Type: (Select One)** Standard Deviation; Standard Error of the Mean **Value:** _____
	Estimation Comments ②	
Other Statistical Analysis ④		

*** Required** **[*] Conditionally required**

① **Use the checkboxes to select the Arms/Groups (pre-populated from the Outcome Measure) involved in the statistical analysis.**

② **(Optional) Include any relevant information about the row above (e.g., the null hypothesis, details of the power calculation, adjustment for multiple comparisons, the *a priori* threshold for statistical significance, the direction of the comparison). Do not include written results or conclusions.**

③ **If a non-inferiority or equivalence analysis, information on the definition of the non-inferiority or equivalence margin is required.**

④ **If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results of the scientifically appropriate test of statistical significance.**

Statistical Analysis Plan (SAP)

Given the study is an open label single-arm interventional study without a control group, the change of attributes (whole blood NAD/NR levels, PBMC pro-inflammatory cytokine expression levels, mitochondrial oxygen consumption rate) of each study subject before and after intervention (oral nicotinamide riboside) will be analyzed by the pairwise Student's t-test. If the distribution of the data passes the normality test, a parametric t-test will be used, otherwise a non-parametric t-test will be used.