

Statistical Analysis Plan

Study Title:	Genetic Determinants of the Coronary Microvascular Obstruction in Percutaneous Coronary Interventions
Protocol Number:	CMVO-SNP-2022
Study Number:	NCT05355532
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1. Primary Objective: to identify statistically significant associations between selected SNPs and CMVO development post-PCI in STEMI patients.

2. Data Preparation

2.1 Data Collection

- Genetic data: SNP genotypes (binary: variant present/absent)
- Clinical data:
 - demographics
 - angiographic parameters
 - laboratory values
 - procedural details
 - hospitalization outcomes
 - CMVO presence/absence

2.2 Data Cleaning

- Missing data: exclude samples with >10% missing SNP calls.
- Quality control: Hardy-Weinberg equilibrium testing ($p < 0.05$ threshold for exclusion)

3. Statistical Methods

3.1 Statistical Analysis

- Univariate analysis:
 - McNemar's test (matched case-control design) for categorical SNPs
 - Odds ratios (OR) with 95% confidence intervals
- Multivariate analysis:
 - Conditional logistic regression
 - OR with 95% confidence intervals

3.2 Sensitivity Analysis

- Re-run analysis using dominant/recessive genetic models

4. Outcome Measures

- Primary endpoint: CMVO
- Secondary endpoints:
 - In-hospital mortality

- Left Ventricle Ejection Fraction
- Ventricular fibrillation
- N-terminal Pro-brain Natriuretic Peptide
- Six-minute Walk Test

5. Statistical Software

- R

6. Sample Size Justification

- 80 patients (40 CMVO+/40 CMVO–) provides:
 - 80% power to detect $OR \geq 4.0$ ($\alpha=0.05$, two-tailed)
 - Assumes SNP prevalence = 12–69% (average 50%)

7. Data Presentation

- Tables:
 - Baseline characteristics (Me [Q1; Q3] for continuous; n (%) for categorical)
 - SNP frequencies by group
 - Multivariate ORs for CMVO predictors
- Figures:
 - Flowchart of patient inclusion
 - Forest plot of significant SNPs

8. Ethical Considerations

- All analyses will use anonymized data (patient serial numbers only).
- Protocol deviations documented in CONSORT flowchart.
- Approval:

Local Ethics Committee Protocol Version: 1.0