Evolocumab in Patients With Acute MI
NCT04082442 7/14/2021

Evolocumab in Patients with Acute Myocardial Infarction (NCT04082442)

Study Statistics

Cover Sheet

Title: Evolocumab in Patients with Acute Myocardial Infarction: A Double-blind, Prospective, Randomized, Placebo-Controlled Study

Study Type: Interventional (Randomized, Double-Blind, Placebo-Controlled)

Population: Patients with acute myocardial infarction receiving high-intensity statin therapy

Sample Size: 100 participants (50 per arm: Evolocumab vs. Placebo)

Primary Outcome: Percent change in LDL-cholesterol (LDL-C) from baseline to 30 days

Key Secondary Outcome: Change in myocardial inflammation measured by FDG-PET (mean Standardized Uptake Value, SUV) from baseline to 30 days

Analysis Population: All randomized participants with evaluable baseline and follow-up data

Primary Endpoint Analysis

Endpoint Definition: Difference in the mean percent change in LDL-C from baseline (pre-randomization) to 30 days in the evolocumab and placebo groups.

Statistical Method:

- Mean ± SD LDL-C at baseline and 30 days will be summarized for each group.
- Between-group comparisons will use an independent-samples t-test (two-sample test of means).
- Percent change will be calculated as: ((LDL-C30d − LDL-Cbaseline) / LDL-Cbaseline) × 100.
- Two-sided $p < 0.05$ will indicate statistical significance.
- Results will also be presented as mean differences with 95% confidence intervals.

Power Considerations: Assuming baseline LDL-C ≈ 110 mg/dL, 50% reduction with standard statin therapy, and an additional 50% reduction with evolocumab, a sample size of 50 per group provides >99% power (one-sided $\alpha = 0.05$) to detect a 13.5 mg/dL absolute LDL-C difference.

Secondary Endpoint Analysis

Endpoint Definition: Change in inflammation quantified as mean FDG-PET Standardized Uptake Value (SUV) from baseline (index hospitalization) to 30 days in the evolocumab and placebo groups.

Statistical Method:

- For within-group change: paired t-test or Wilcoxon signed-rank test (if non-normal).
- For between-group comparisons: independent-samples t-test or Mann–Whitney U test.
- Data will be presented as mean ± SD and mean difference (95% CI).
- Significance defined as two-sided $p < 0.05$.

Power Considerations: Assuming mean ± SD = 35.4 ± 18.1 (Ripschler et al.), with 50 participants per arm, there is 80% power to detect a 30% difference in mean SUV between groups. For vascular inflammation (TBR, target-to-background ratio), published differences of 10–15% yield >88–99% power for n = 50 per group.