

Effect of the PCSK9 Inhibitor Evolocumab on Cardiovascular Outcomes (OSLER-1 and -2)

Purpose: Long-term safety and tolerability of evolocumab, a monoclonal antibody designed for the treatment of hyperlipidemia.

Trial Design: Interventional, phase 3, open label, multi-center, randomized 2:1 evolocumab + standard of care (SoC) vs. standard of care alone; safety and efficacy study. N = 4465 . 11.1 month median f/u.

Primary Endpoint: Incidence of adverse events (death, MI, angina, stroke, TIA, hospitalization and coronary revascularization at.

Trial Results

LDL-C Reduction with evolocumab + SoC vs. SoC

61% decrease, $p < 0.001$
(120 mg/dl reduced to 48 mg/dl avg.)

MACE at 1 year: SoC vs. evolocumab + SoC

53% reduction, $p = 0.003$
(2.18% vs. 0.95%)

Conclusions: Evolocumab added to standard of care demonstrated a reduction of LDL-C and major cardiovascular events at 1 year f/u. The drug was safe and tolerated in this trial.