

Inclusiecriteria cholesterol onderzoek uit met een PCSK-9 remmer (Repatha – evolocumab).
Interne geneeskunde – VESALIUSDr. S.C.C. Hartong (vasculair geneeskundige) en Drs. R.J.M. van Leendert.

- A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate the Impact of Evolocumab on Major Cardiovascular Events in Patients at High Cardiovascular Risk Without Prior Myocardial Infarction or Stroke
- **Key inclusion criteria**
 - Adult subjects ≥ 50 years (men) or ≥ 55 years (women) to < 80 years of age
 - Subjects must have an LDL-C ≥ 100 mg/dL (≥ 2.6 mmol/L) or non-HDL-C ≥ 130 mg/dL (≥ 3.4 mmol/L) at screening, after ≥ 4 weeks of optimized lipid-lowering therapy
 - Diagnostic evidence of at least 1 of the following (A – D) at screening:
 - A. Significant coronary artery disease meeting at least 1 of the following criteria:
 - History of coronary revascularization with multi-vessel coronary disease
 - Significant coronary disease without prior revascularization as evidenced by either a $\geq 70\%$ stenosis of at least 1 coronary artery, $\geq 50\%$ stenosis of 2 or more coronary arteries, or $\geq 50\%$ stenosis of the left main coronary artery
 - known coronary artery calcium score ≥ 100
 - B. Significant atherosclerotic cerebrovascular disease meeting at least 1 of the following criteria:
 - prior transient ischemic attack with $\geq 50\%$ carotid stenosis
 - carotid artery stenosis of $\geq 70\%$ or 2 or more $\geq 50\%$ stenosis
 - prior carotid artery revascularization
 - C. Significant peripheral arterial disease meeting at least 1 of the following criteria
 - $\geq 50\%$ stenosis in a limb artery
 - history of abdominal aorta treatment (percutaneous and surgical)
 - ankle brachial index (ABI) ≥ 0.8
 - D. Diabetes mellitus with at least 1 of the following:
 - known microvascular disease, defined by diabetic nephropathy or treated retinopathy.
 - chronic treatment with insulin
 - diabetes diagnosis > 10 years ago
- **Key exclusion criteria**
 - MI or stroke prior to randomization

Study Schema

Figure 2-1. Study Schema

