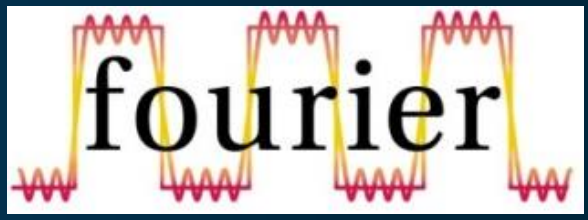


FOURIER

Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk

https://clinicaltrials.gov/ct2/show/NCT01764633

FOURIER: Purpose

The primary hypothesis is that additional LDL-C lowering with Evolocumab when used in addition to other treatment for dyslipidemia is well tolerated and decreases the risk of cardiovascular death, myocardial infarction, hospitalization for unstable angina, stroke, or coronary revascularization in subjects with clinically evident cardiovascular disease.

FOURIER:
Outcome Measures:

Primary

- The primary endpoint is the time to cardiovascular death, myocardial infarction, hospitalization for unstable angina, stroke, or coronary revascularization whichever occurs first. [Time Frame: 5 years]

Secundary

- Time to cardiovascular death, myocardial infarction, or stroke, whichever occurs first
- Time to cardiovascular death
- Time to death by any cause
- Time to first myocardial infarction
- Time to first stroke
- Time to first coronary revascularization
- Time to cardiovascular death or first hospitalization for worsening heart failure, whichever occurs first
- Time to ischemic fatal or non-fatal stroke or TIA, whichever occurs first

https://clinicaltrials.gov/ct2/show/NCT01764633

FOURIER: Criteria

Inclusion

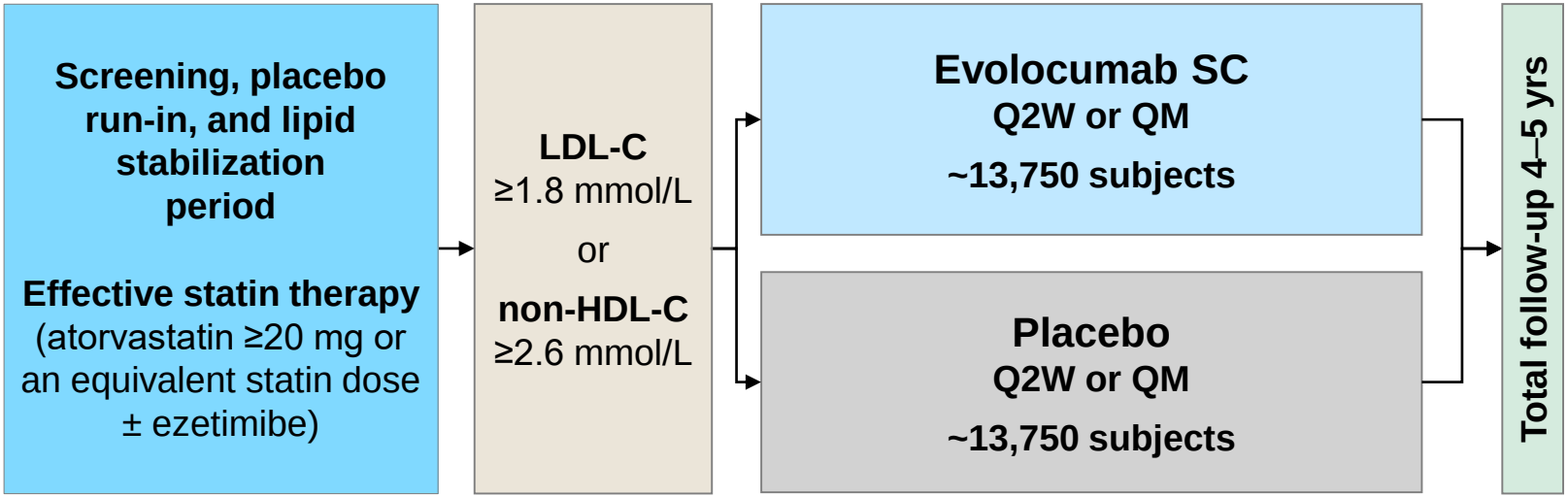
- Male or female ≥ 40 to ≤ 85 years of age
- History of clinically evident cardiovascular disease at high risk for a recurrent event
- Fasting LDL-C ≥ 70 mg/dL (≥ 1.8 mmol/L)) or non-HDL-C ≥ 100 mg/dL (> 2.6 mmol/L)
- Fasting triglycerides ≤ 400 mg/dL (4.5 mmol/L)

Exclusion

- NYHA class III or IV, or last known left ventricular ejection fraction < 30%
- Uncontrolled hypertension
- Uncontrolled or recurrent ventricular tachycardia
- Untreated hyperthyroidism or hypothyroidism
- Homozygous familial hypercholesterolemia
- LDL or plasma apheresis

FOURIER: Design

>27,500 patients with clinically evident CVD (prior MI, stroke or PAD)
Age 40 to 85 years, ≥1 other high-risk features



Primary endpoint: CV death, MI, hospitalization for UA, stroke, coronary revascularization

https://clinicaltrials.gov/ct2/show/NCT01764633?term=NCT01764633

Sabatine M, et al. N Engl J Med 2015;372:1500–9. (Suppl.):1–21.)

Press release
February 2, 2017

Amgen today announced that the **FOURIER trial** evaluating whether evolocumab reduces the risk of cardiovascular events in patients with clinically evident atherosclerotic cardiovascular disease (ASCVD) met its primary composite endpoint (cardiovascular death, non-fatal myocardial infarction (MI), non-fatal stroke, hospitalization for unstable angina or coronary revascularization)

and the key secondary composite endpoint (cardiovascular death, non-fatal MI or non-fatal stroke).

No new safety issues were observed..