EBBINGHAUS

Evaluating PCSK9 Binding antiBody Influence oN coGnitive HeAlth in High cardiovascUlar Risk Subjects

https://clinicaltrials.gov/ct2/results?term=EBBINGHAUS

EBBINGHAUS: Purpose

This study evaluates change over time in neurocognitive testing in subjects receiving statin therapy in combination with evolocumab, compared with subjects receiving statin therapy in combination with placebo.

EBBINGHAUS:
Outcome Measures:

Primary

- Mean Change from baseline over time in Spatial Working Memory (SWM) index of executive function

Secundary

- Mean Change from baseline over time in Spatial Working Memory (SWM) between-errors score
- Mean Change from baseline over time in Paired Associated Learning (PAL) total errors adjusted.
- Mean Change from baseline over time in Reaction Time (RTI) median 5-choice reaction time

EBBINGHAUS: Criteria

Inclusion

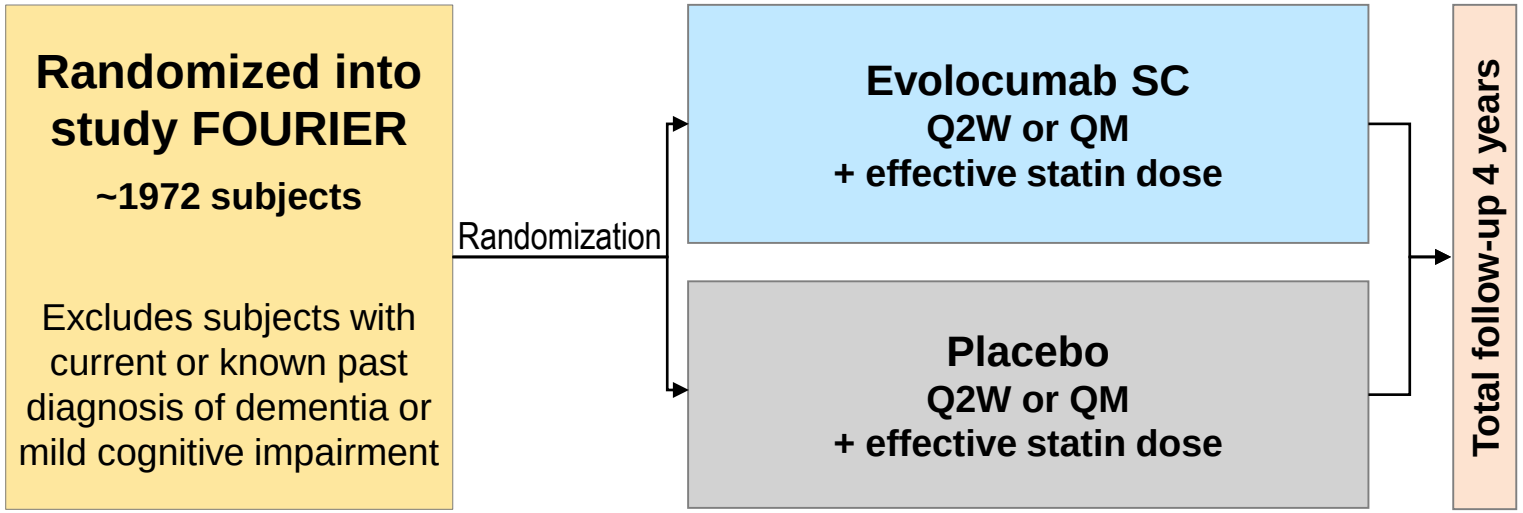
- Randomized into Study 20110118 (FOURIER)

Exclusion

- Current or known past diagnosis of dementia or mild cognitive impairment (MCI)

EBBINGHAUS: Design

- Sub-study of FOURIER



- Primary outcome measure: mean change from baseline over time in SWM index of executive function
- Secondary outcome measures:
  - Mean change from baseline over time in SWM between error scores
  - Mean change from baseline over time in PAL total errors adjusted
  - Mean change from baseline over time in RTI median 5-choice reaction time

PAL, paired associated learning; Q2W, once every 2 weeks; QM, once monthly; RTI, reaction time; SPW, special working memory.

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..

The EBBINGHAUS cognitive function trial conducted in FOURIER patients also achieved its primary endpoint, demonstrating that Repatha was non-inferior to placebo for the effect on cognitive function.