COMPASS

Rivaroxaban for the Prevention of Major Cardiovascular Events in Coronary or Peripheral Artery Disease

https://clinicaltrials.gov/ct2/show/NCT01776424

COMPASS: Purpose

The primary purpose of this study is to evaluate whether treatment with rivaroxaban and aspirin or rivaroxaban alone is better than aspirin alone in prevention of heart attacks, stroke or cardiovascular death in patients with coronary or peripheral artery disease.

COMPASS: Outcome Measures

Primary

- Time from randomization to the first occurrence of either myocardial infarction, stroke, or cardiovascular death
- Time from randomization to the first occurrence of major bleeding (modified International Society on Thrombosis and Haemostasis)

Secundary

- Time from randomization to first occurrence of either Coronary heart disease death, myocardial infarction, ischemic stroke, acute limb ischemia
- Time from randomization to first occurrence of either Cardiovascular death, myocardial infarction, ischemic stroke, acute limb ischemia
- Time from randomization to first occurrence of all-cause mortality

COMPASS: Criteria

Inclusion

- Coronary or peripheral artery disease

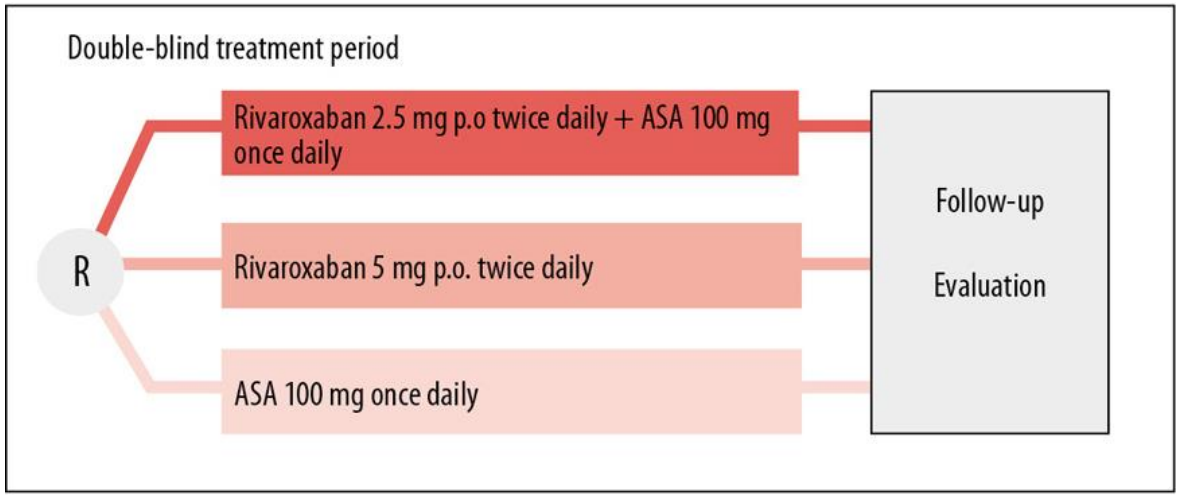
  Patients with coronary artery disease must also meet at least one of the following:
  - Age ≥65, or
  - Age <65 and documented atherosclerosis or revascularization involving at least 2 vascular beds, or at least 2 additional risk factors

Exclusion

- Need for dual antiplatelet therapy, other non-aspirin antiplatelet therapy or oral anticoagulant therapy
- Stroke within 1 month or any history of hemorrhagic or lacunar stroke
- Severe heart failure with known ejection fraction <30% or New York Heart Association (NYHA) class III or IV symptoms
- Estimated glomerular filtration rate (eGFR)<15 mL/min

COMPASS: Design

- Randomized placebo-controlled phase III study, event driven, expected duration 3–4 years
- 27,400 patients ≥18 years with documented atherosclerosis related to CAD or PAD plus one of the following inclusion criteria:
  - age ≥65 years
  - age <65 years plus documented atherosclerosis in at least two vascular beds or at least 2 additional risk factors



Active treatment:

- Stratum 1: rivaroxaban 2.5 mg p.o. twice daily plus ASA 100 mg once daily
- Stratum 2: rivaroxaban 5 mg p.o twice daily plus ASA placebo

Control treatment:

- ASA 100 mg once daily plus rivaroxaban placebo

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COMPASS: Press release

February 8, 2017

Berlin, February 8, 2017 Janssen Research & Development, LLC today announced that the Phase III trial **COMPASS** evaluating the efficacy and safety of rivaroxaban (Xarelto®) for the prevention of major adverse cardiac events (MACE) including cardiovascular death, myocardial infarction and stroke in patients with coronary artery disease (CAD) or peripheral artery disease (PAD) **has met its primary endpoint ahead of time**.

Following a planned interim analysis conducted by the independent Data Monitoring Committee (DMC), the DMC **recommended to stop the trial early as the primary MACE endpoint has reached its prespecified criteria for superiority.**

Owing to the magnitude of effect and the confirmation of the existing safety profile of rivaroxaban