

Section C. Definition of high risk of cardiovascular events

High risk of cardiovascular events was defined as the presence of ≥ 1 of the following:

- History of myocardial infarction >2 months prior to informed consent
- Evidence of multi-vessel coronary artery disease i.e. in ≥ 2 major coronary arteries or the left main coronary artery, documented by any of the following:
 - Presence of significant stenosis: $\geq 50\%$ luminal narrowing during angiography (coronary or multi-slice computed tomography)
 - Previous revascularization (percutaneous transluminal coronary angioplasty \pm stent or coronary artery bypass graft >2 months prior to consent
 - The combination of revascularization in one major coronary artery and significant stenosis ($\geq 50\%$ luminal narrowing) in another major coronary artery
- Evidence of single-vessel coronary artery disease, $\geq 50\%$ luminal narrowing during angiography (coronary or multi-slice computed tomography) not subsequently successfully revascularized, with at least 1 of the following:
 - A positive non-invasive stress test for ischemia
 - Hospital discharge for unstable angina ≤ 12 months prior to consent
- Unstable angina >2 months prior to consent with evidence of single- or multi-vessel coronary artery disease
- History of stroke (ischemic or hemorrhagic) >2 months prior to consent
- Occlusive peripheral artery disease documented by any of the following:
 - Limb angioplasty, stenting, or bypass surgery
 - Limb or foot amputation due to circulatory insufficiency
 - Evidence of significant peripheral artery stenosis ($>50\%$ on angiography, or $>50\%$ or hemodynamically significant via non-invasive methods) in 1 limb
 - Ankle brachial index <0.9 in ≥ 1 ankle