A Multicentre, Open-Label, Randomised Controlled Clinical Trial to Assess the Efficacy and Safety of Appropriate Target Values for Lipid Management in Patients who Have Mild to Moderate Stenotic Lesions with High-Risk Plaques in Coronary Arteries: Study Protocol

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Aims: To investigate the efficacy of strict lipid management by secondary prevention high-risk criteria in preventing major cardiovascular events and progression of coronary artery stenosis in study subjects without proven history of coronary artery diseases (CAD) who have non-occlusive lesions with unstable plaques or severe calcification detected by coronary artery CT (CACT), in comparison with standard lipid management as per the primary prevention criteria.

Design and methods: This is a multicentre, open-label, randomised controlled parallel-group clinical study. Patients with mild to moderate stenotic lesions with positive remodelling or severe calcification, but without any history of CAD, will be randomly allocated to group A (reduce LDL cholesterol to <120–160 mg/dl, according to the primary prevention criteria based on the Japanese Guideline for Prevention of Atherosclerotic Cardiovascular Diseases) and group B (reduce LDL cholesterol to <70 mg/dl, according to the secondary prevention criteria at a high risk based on the guideline). They will be strictly managed to achieve the LDL cholesterol targets. We will follow up and evaluate the composite endpoints consisting of major cardiovascular events (death from coronary artery disease, nonfatal MI, operation for coronary revascularisation, and stroke) and stenosis progression or new stenosis development for 3 years.

Conclusion: Our study will contribute to the development of a better preventive therapy for patients who have non-occlusive lesions with unstable plaques or severe calcification detected on CACT. ■