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Food and Drug Administration Approved Statin for Primary Prevention of Stroke Except Aspirin

The Food and Drug Administration (FDA) has approved rosuvastatin (Crestor) for primary prevention of cardiovascular disease, making it the first statin to receive this indication. This year, Korean FDA has approved statin for primary prevention of cardiovascular and stroke. However the indication is relatively strict as C-reactive protein of 2 mg/L over and history of cardiovascular risk factors as hypertension compared US.

Aspirin has been known to be ineffective for primary prevention of cardiovascular events in high-risk diabetics, by two research-papers, two years ago. One report showed that, among patients with diabetes and asymptomatic peripheral arterial disease, aspirin did not reduce primary fatal and non-fatal cardiovascular events compared with placebo [hazard ratio 0.98, 95% confidence interval (CI) 0.76 to 1.26], reported Jill Belch and colleagues of the University of Dundee online in BMJ. In the second report, which was conducted in Japan, low-dose aspirin did not seem to prevent cardiovascular events in people with type 2 diabetes, although researchers noted a possible benefit in the older participants. The study was published Nov. 9 in JAMA by Ogawa H, et al. Therefore, Food and Drug Administration (FDA) did not approve aspirin for primary prevention of stroke and cardiovascular disease.

The new labeling for statin, recommended by an FDA advisory panel late last year, also marks the first time that a drug label will include an indication based on the biomarker highly-sensitive C-reactive protein (CRP), an inflammatory marker. The new indication would be for men 50 or older and women 60 or older who have fasting low density lipoprotein (LDL) of less than 130 mg/dL, a highly-sensitive CRP of 2.0 mg/L or greater, triglycerides of less than 500 mg/dL, and no prior history of heart attack or stroke, or coronary heart disease risk. Critical study, a randomized Justification for the Use of statins in Primary prevention: and Intervention Trial Evaluating Rosuvastatin (JUPITER) trial, contains placebo-controlled trial of 17,802 men and women with a mean age of 66 and no history of atherosclerosis. All participants had LDL of less than 130 mg/dL and a highly-sensitive CRP concentration of 2 mg/L or higher. Patients were ranomized to 20 mg of rosuvastatin for 1.9 years, which reduced median LDL cholesterol to 55 mg/dL, down from a median of 108 mg/dL at baseline. The corresponding relative reduction in the rate of myocardial infarction, stroke, arterial revascularization, or cardiovascular death was 44% ($p<0.00001$). The number needed to treat to avoid one cardiovascular event was 25. Those results, according to Melvyn Rubenfire of the University of Michigan, were a "home run for JUPITER," but it is not clear whether the results would be the same with another statin. And there were some risks associated with rosuvastatin, including 13 deaths due to gastrointestinal disorders in the rosuvastatin arm, and 18 patients reported experiencing a "confused state" while taking the drug.

The most troubling adverse event, however, was an uptick in investigator-reported, new onset diabetes mellitus in the treatment arm, 2.8% versus 2.5%, for a hazard ratio of 1.27 (95% CI 1.05 to 1.53, $p=0.015$).

Rosuvastatin in marketed by AstraZeneca, which also sponsored the JUPITER trial.

