The Fixed-dose Combination Drug for Secondary Cardiovascular Prevention project: Improving equitable access and adherence to secondary cardiovascular prevention with a fixed-dose combination drug. Study design and objectives.


Source

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Abstract

In spite of advances in prevention and treatment, the burden of cardiovascular diseases is increasing. A fixed-dose combination (FDC) pill, or "polypill," composed of evidence-based drugs has been proposed as a means of improving cardiovascular prevention by reducing cost and increasing patient adherence to treatment. The aim of the FOCUS project, funded by the 7th Framework Programme of the European Commission, is to characterize the factors that underlie inadequate secondary prevention and to test a new FDC. To achieve these goals, a 9-member consortium has been constituted, including institutions from Argentina, France, Italy, Spain, and Switzerland. FOCUS Phase-1 will examine factors potentially related to lack of adequate secondary prevention in 4,000 post-myocardial infarction (MI) patients and analyze the relationship between these factors and patient treatment adherence. Primary end points will be (1) the percentage of patients receiving aspirin, angiotensin-converting enzyme inhibitors, and statins and (2) adherence to treatment measured by the Morisky-Green test. FOCUS Phase-2 is a randomized trial that will compare adherence to treatment in 1,340 post-myocardial infarction patients either receiving an FDC comprising aspirin (100 mg), ramipril (2.5, 5, or 10 mg), and simvastatin (40 mg) or receiving the same 3 drugs separately.