

Clopidogrel with aspirin doesn't prevent more small strokes, may increase risk of bleeding, death

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The anti-blood clot regimen that adds the drug clopidogrel (Plavix) to aspirin treatment is unlikely to prevent recurrent strokes and may increase the risk of bleeding and death in patients with subcortical stroke according to late-breaking research presented at the American Stroke Association's International Stroke Conference 2012.

Because of these preliminary results, researchers ended the anti-clotting part of the [Secondary Prevention](#) of Small Subcortical Strokes Trial (SPS3) in August 2011. The part of the study that examines the effect of high blood pressure treatments will continue. The SPS3 trial is the first large-scale study of patients with subcortical strokes, which occur when small blood vessels deep in the middle of the brain are blocked, damaging small areas of [brain tissue](#). This type of stroke affects about 150,000 Americans each year, and is the most common cause of [vascular dementia](#) according to Oscar Benavente, M.D., lead author of the study and a professor of neurology at Canada's University of British Columbia in Vancouver, British Columbia.

[American Heart Association](#)/American Stroke Association guidelines for preventing [recurrent strokes](#) recommend anti-clotting medications like aspirin, the customary treatment, or other clot preventives like [clopidogrel](#), but not the combination of aspirin plus clopidogrel.

Treatments have not been compared in patients with subcortical strokes

specifically.

In the United States, stroke is the No. 4 killer and a leading cause of disability among adults.

Beginning in March 2003, the SPS3 study included 3,020 patients at 81 sites in the United States, Canada, Spain, Mexico and South America. [Stroke patients](#) were randomly assigned within 180 days of symptom onset to receive aspirin and clopidogrel or aspirin plus placebo daily. Neither researchers nor patients knew who received placebo or the study drug.

Preliminary findings showed that the risk of bleeding nearly doubled among patients on the clopidogrel/aspirin combination, compared to those on aspirin and placebo: Aspirin plus placebo had a 1.1 percent of bleeding risk per year and aspirin plus clopidogrel a 2.1 percent bleeding risk per year – largely from major bleeds somewhere other than in the brain.

Similarly, the annual risk of death was greater with the combined therapy: Aspirin plus placebo had a 1.4 percent risk of death and aspirin plus clopidogrel had a 2.1 percent risk of death.

There was no difference in stroke recurrence in both treatment arms.

"These interim results do not support the use of combination clopidogrel plus aspirin for secondary stroke prevention in patients with small subcortical strokes," the researchers said.

Provided by American Heart Association

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