

# Abstract

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## Aspirin for prevention of cardiovascular events in a general population screened for a low ankle brachial index: a randomized controlled trial.

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**CONTEXT:** A low ankle brachial index (ABI) indicates atherosclerosis and an increased risk of cardiovascular and cerebrovascular events. Screening for a low ABI can identify an asymptomatic higher risk group potentially amenable to preventive treatments.

**OBJECTIVE:** To determine the effectiveness of aspirin in preventing events in people with a low ABI identified on screening the general population.

**DESIGN, SETTING, AND PARTICIPANTS:** The Aspirin for Asymptomatic Atherosclerosis trial was an intention-to-treat double-blind randomized controlled trial conducted from April 1998 to October 2008, involving 28,980 men and women aged 50 to 75 years living in central Scotland, free of clinical cardiovascular disease, recruited from a community health registry, and had an ABI screening test. Of those, 3350 with a low ABI ( $\leq 0.95$ ) were entered into the trial, which was powered to detect a 25% proportional risk reduction in events.

**INTERVENTIONS:** Once daily 100 mg aspirin (enteric coated) or placebo.

**MAIN OUTCOME MEASURES:** The primary end point was a composite of initial fatal or nonfatal coronary event or stroke or revascularization. Two secondary end points were (1) all initial vascular events defined as a composite of a primary end point event or angina, intermittent claudication, or transient ischemic attack; and (2) all-cause mortality.

**RESULTS:** After a mean (SD) follow-up of 8.2 (1.6) years, 357 participants had a primary end point event (13.5 per 1000 person-years, 95% confidence interval [CI], 12.2-15.0). No statistically significant difference was found between groups (13.7 events per 1000 person-years in the aspirin group vs 13.3 in the placebo group; hazard ratio [HR], 1.03; 95% CI, 0.84-1.27). A vascular event comprising the secondary end point occurred in 578 participants (22.8 per 1000 person-years; 95% CI, 21.0-24.8) and no statistically significant difference between groups (22.8 events per 1000 person-years in the aspirin group vs 22.9 in the placebo group; HR, 1.00; 95% CI, 0.85-1.17). There was no significant difference in all-cause mortality between groups (176 vs 186 deaths, respectively; HR, 0.95; 95% CI, 0.77-1.16). An initial event of major hemorrhage requiring admission to hospital occurred in 34 participants (2.5 per 1000 person-years) in the aspirin group and 20 (1.5 per 1000 person-years) in the placebo group (HR, 1.71; 95% CI, 0.99-2.97).

**CONCLUSION:** Among participants without clinical cardiovascular disease, identified with a low ABI based on screening a general population, the administration of aspirin compared with placebo did not result in a significant reduction in vascular events.

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