

ADAPTABLE: The Aspirin Study

What is the purpose of the study?

The ADAPTABLE study will compare the effectiveness of 81mg vs 325mg aspirin for secondary prevention in patients with atherosclerotic cardiovascular disease. Although most studies have found that lower-dose aspirin is associated with less bleeding, these studies have provided contradictory evidence regarding the comparative effectiveness of low vs higher dose aspirin in reducing ischemic events.

Who is eligible to participate?

Adult patients at UNC with coronary heart disease who are at elevated risk are eligible to participate. Elevated risk is determined by the presence of any one or more of these risk factors:

- * Age \geq 65
- * Creatinine \geq 1.5 mg/dL
- * Diabetes mellitus
- * Known 3-vessel CAD
- * Cerebrovascular disease
- * Peripheral arterial disease
- * Current smoker
- * Known LVEF $<$ 50%
- * Chronic systolic or diastolic heart failure
- * SBP \geq 140 (within the past 12 months)
- * LDL \geq 130 (within the past 12 months)

What is the process for screening and enrollment?

Patients will be pre-screened for aspirin allergies, anticoagulant use, and for any contraindications to taking aspirin. Additional screening occurs via the study's web portal during enrollment. After a patient enrolls, the principal investigator will review the patient's chart and contact their provider about their participation and randomized aspirin dose. Eligible participants will receive a unique code from the research team to participate.

Who is funding this study?

The Patient Centered Outcomes Research Institute (PCORI) is funding this national multi-center study. The national enrollment goal is 20,000 patients, with 500 enrolled by our UNC team from April 2017 through April 2018.

Will participants be compensated?

Patients will be mailed a one-time payment of \$25 upon completion of the first follow-up survey. Patients will be responsible for purchasing their assigned dose of over the counter aspirin.

What is my role as a physician, nurse practitioner, or physician assistant?

Patient enrollment in ADAPTABLE should not affect your day to day work as a provider. Besides a potential change in aspirin dose, there will be no other changes to a participant's medical care.

- When a patient chooses to enroll, their provider will be notified via EPIC.
- There is no blinding, and we will communicate the assigned aspirin dose.
- Patients are not required to make any study specific visits to a healthcare provider.

Who do I contact if I have questions?

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Adaptable

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