Alliance A011502: A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Her2 Negative Breast Cancer: The ABC Trial

WY Chen, EP Winer, AH Partridge, LA Carey, T Openshaw, M Carvan, C Matyka,
K Visvanathan, B Symington, MD Holmes

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Rationale

Compelling in-vitro and in-vivo evidence suggest that aspirin may have anti-tumor effect. Multiple epidemiologic studies have reported improved breast cancer survival among regular aspirin users compared to non-users. Pooled data from randomized trials of aspirin for cardiovascular disease have also reported a decreased risk of metastatic cancer among aspirin users, mainly driven by a decreased risk of metastatic adenocarcinoma (RR 0.52 (95% CI 0.35-0.75)). However in order for aspirin to become standard of care, the exact benefits and risks for breast cancer survivors would need to be confirmed in a randomized controlled trial. Even if clinical effects were modest, the global impact would be substantial since aspirin is inexpensive and widely available.

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Objective

Primary

- To compare the effect of aspirin (300 mg daily) versus placebo upon invasive disease free survival (iDFS) in early stage HER2 negative breast cancer patients.

Secondary

- To compare the effect of aspirin versus placebo on: a) distant disease-free survival; b) overall survival; and c) cardiovascular disease.
- To compare the toxicity of aspirin versus placebo.
- To assess adherence to aspirin and placebo.
- To bank tumor and germline deoxyribonucleic acid (DNA), plasma and urine collected at baseline and sequential plasma and urine collected 2 years later for future measurement of inflammatory markers.
- To determine if there are subgroups of participants characterized by lifestyle factors associates with greater inflammation for whom there is greater benefit of aspirin versus placebo upon iDFS.

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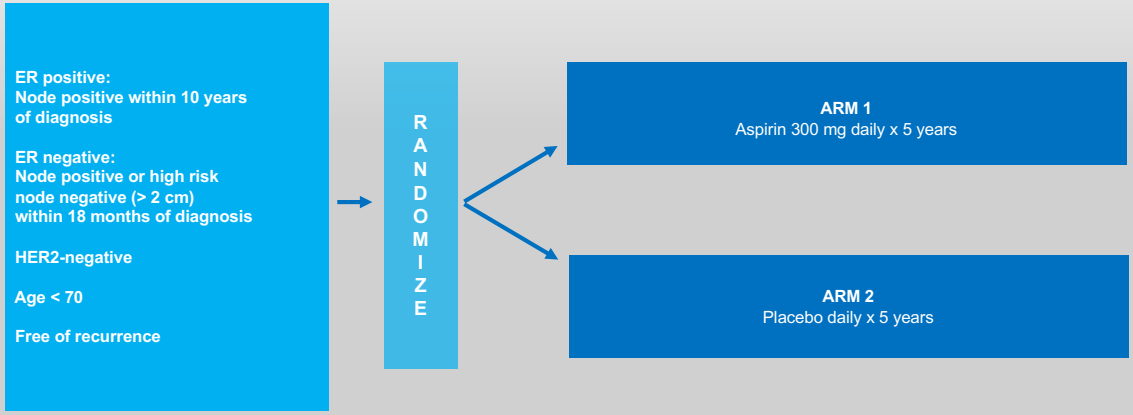
Study Schema



Target accrual: 2,936

Power and Sample size: Assuming 381 iDFS events and 5-year iDFS on placebo of 77%, 80% power to detect HR 0.75

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Study Status

- Activated December 2016
- Accrual as of April 2019: 1,347
- 1175+ sites approved
- Open in ECOG-ACRIN, NRG, SWOG, and Health Canada
- Clinical trials.gov ID NCT02927249

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Key Eligibility Criteria

- HER-2 negative
- ER positive: Node positive within 10 years of diagnosis
- ER negative: Node positive or high risk node negative (> 2 cm) within 18 months of diagnosis
- Prior adjuvant treatment with chemotherapy and/or endocrine therapy, as determined by treating physician
- Regular NSAID/aspirin use allowed if stopped for 30 prior to study entry
- Age 18-70

Exclusion Criteria

- History of prior stroke
- History of significant GI bleeding
- No concurrent anticoagulation with warfarin, heparin, clopidogrel, or oral direct thrombin inhibitors
- History of atrial fibrillation or myocardial infarction
- History of grade IV hypertension
- Chronic daily use of oral steroids
- No prior malignancy in past 5 years

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