Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

FAST FACTS

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

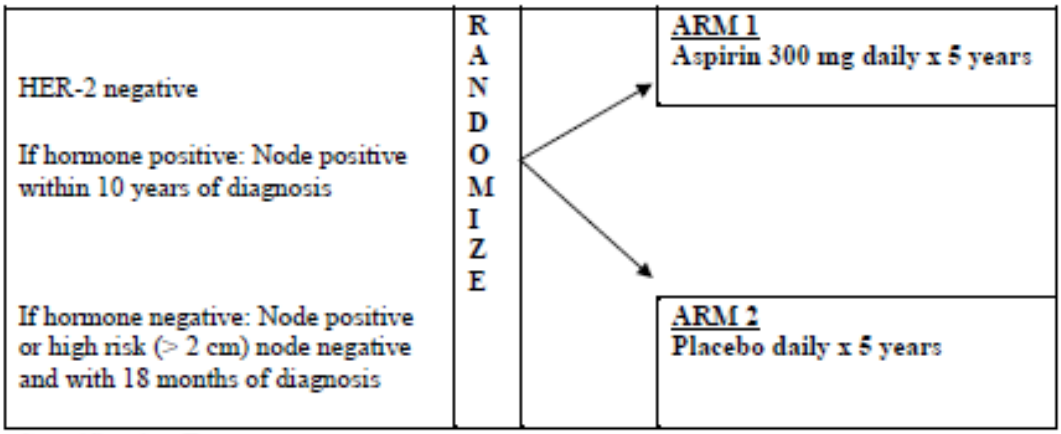
A011502: A RANDOMIZED PHASE III DOUBLE BLINDED PLACEBO CONTROLLED TRIAL OF ASPIRIN AS ADJUVANT THERAPY FOR NODE POSTIVE HER2 NEGATIVE BREAST CANCER: THE ABC TRIAL

Eligibility Criteria

1. Histologic documentation of women or men with HER2 negative breast carcinoma and free of recurrence. If neoadjuvant therapy was received, either initial clinical stage (determined by physical and or radiologic examination) or post-operative pathologic stage can be used for eligibility purposes, with the higher stage determining eligibility. Histologic documentation of node positivity is required for ER/PR positive tumors.
   Bilateral or synchronous breast cancers are allowed, as long as both cancers are HER2 negative and at least one of the cancers meets eligibility.
2. If ER and PR negative, tumor must be node positive or >2 cm and node negative. Patients must be registered within 18 months of diagnosis. pN1mic is eligible.
   If ER and/or PR positive, tumor must be node positive and within 10 years of diagnosis. pN1mic is eligible.
3. Prior adjuvant treatment with chemotherapy and/or endocrine therapy, as determined by the treating physician, is allowed. The last dose of chemotherapy or radiation therapy must be at least 30 days prior to study registration. Concurrent hormonal therapy is allowed.
4. Regular NSAID/aspirin use at any dose (including baby aspirin) (defined as ≥ 5 days per week) is allowed if aspirin and/or NSAIDs are stopped for 30 days prior to study entry and throughout the study period. Participants will be encouraged to use acetaminophen for minor pain and fever.
5. Age > 18 and < 70 years of age.
6. ECOG performance status 0-2.
7. Patients with a prior history of gastric/duodenal ulcers documented on endoscopy can be enrolled as long as the ulcers did not cause bleeding requiring a blood transfusion/major intervention.
   For patients who are Helicobacter pylori positive, a course of Helicobacter pylori eradication treatment must have been completed.
8. No history of GI bleeding requiring a blood transfusion, endoscopic or operative intervention.
9. No history of any prior stroke (hemorrhagic or ischemic).
10. No concurrent anticoagulation with warfarin, heparin/heparin analogues, clopidogrel, direct thrombin inhibitors, or direct factor XA inhibitors.
11. No history of atrial fibrillation or myocardial infarction.
12. No history of grade 4 hypertension, defined as hypertension resulting in life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis).
13. No chronic (duration >30 days) daily use of oral steroids. Inhaled or topical steroids are allowed.
14. No known allergy to aspirin.
15. No prior invasive malignancy of any type within the past 5 years except for current diagnosis of breast cancer, and any prior diagnosis of basal or squamous cell carcinoma of the skin.
    Prior history of in situ carcinoma is allowed.
    Patients with a prior history of any type of breast cancer greater than 5 years from study screening may participate in this study.

16. Concurrent enrollment on a non-chemotherapy treatment trial will be allowed, as long as that trial allows concurrent daily aspirin use.
17. No history of metastatic breast cancer.

Schema



Stratification Factors
Hormone Receptor status
1) Positive (either ER or PgR positive or unknown)
2) Negative (both ER and PgR negative)

Body Mass Index
1) Less than 30 kg/m^2
2) Greater than or equal to 30 kg/m^2

Breast Cancer Stage*
1) Stage I/II
2) Stage III

Time Since Diagnosis
1) $\leq$ 18 months
2) > 18 months

* Sites can use AJCC 7 or AJCC 8 because the anatomical staging remains unchanged between the versions.

Pre-study parameters:

- History and Progress Notes
- Physical Examination
- Weight, BMI
- PS
- Height
- AE Assessment
- Pulse, Blood pressure
- Fatigue/Uniscale Assessment
- Platelet count

Companion studies: For patients who consent to participate

- Lifestyle Measures of Inflammation assessment
- Tissue, Blood and Urine samples for Future use