

A011502

A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for HER2 Negative Breast Cancer: The ABC Trial

ClinicalTrials.gov Identifier: NCT02927249

Study Background

Trial Description

This randomized phase III trial studies how well aspirin works in preventing the cancer from coming back (recurrence) in patients with human epidermal growth factor receptor 2 (HER2) negative breast cancer after chemotherapy, surgery, and/or radiation therapy. Aspirin is a drug that reduces pain, fever, inflammation, and blood clotting. It is also being studied in cancer prevention. Giving aspirin may reduce the rate of cancer recurrence in patients with breast cancer.

Arms:

Arm I (aspirin): (Experimental): Patients receive aspirin PO QD for five years in the absence of disease progression or unacceptable toxicity.

Arm II (Placebo): (Placebo Comparator): Patients receive placebo PO QD for five years in the absence of disease progression or unacceptable toxicity.

Objectives:

This is a randomized double-blind placebo-controlled phase III trial of aspirin (300 mg daily) in early stage node-positive HER2 negative breast cancer patients.

Patients will be randomized 1:1 within stratum defined by: Hormone Receptor status (HR positive vs HR negative), body mass index (<30 vs ≥30 kg/m²) and stage (Stage II vs III). The primary objective of this trial is to compare the effect of aspirin versus placebo upon invasive disease-free survival (iDFS) in early stage node-positive HER2 negative breast cancer patients.

Secondary objectives

1. To compare the effect of aspirin versus placebo in early stage node-positive HER2 negative breast cancer patients upon:

1. Distant disease-free survival
2. Overall survival
3. Cardiovascular disease (see Section 11.3 in protocol)

2. To compare the toxicity of aspirin versus placebo in early stage node-positive HER2 negative breast cancer patients.
3. To assess adherence to aspirin and placebo among early stage node-positive HER2 negative breast cancer patients.
4. 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.
5. To determine if there are subgroups of participants characterized by lifestyle factors associated with greater inflammation for whom there is greater benefit of aspirin versus placebo upon iDFS.

Patients are followed up to 10 years after study enrollment.

Study Milestones:

Start date: December 8, 2016

Primary Completion Date: December 13, 2021

Publication Information:

Analysis Type: Primary

PubMed ID: 38683596

Citation: Chen WY, Ballman KV, Partridge AH, et al. Aspirin vs Placebo as Adjuvant Therapy for Breast Cancer: The Alliance A011502 Randomized Trial. JAMA. 2024;331(20):1714-1721. doi:10.1001/jama.2024.4840.

Associated Datasets: NCT02927249-D1-Dataset.csv (A011502_NCTN_datashare),
NCT02927249-D2-Dataset.csv (A011502_AEs_Grade3plus)

Dataset Information:

Dataset Name: NCT02927249-D2-Dataset.csv

Description: Dataset NCT02927249-D2 is one of 2 datasets associated with PubMed ID 38683596. This dataset contains data presented in the Grade 3 or higher adverse event table (Table 3). NCT02927249-D1 contains data presented in the baseline characteristics table, primary analysis, and dose modification information.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT02927249-D2-Dataset.csv (A011502 AEs Grade3plus) Data

Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	id		
Arm	arm	Aspirin Placebo	
Cycle	CYCLE	1 2 3 4 5 6 7 8 9 10	
Grade	GRADE	3 4 5	
Toxicity Code	TOXCODE		
Toxicity	tox		
Relationship to Study Meds	REL_SMED	DEFINITE NOT RELATED POSSIBLE PROBABLE UNLIKELY	
General System Organ Class	SOC		