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-D1-Dataset.csv

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

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-D1-Dataset.csv (A011502_NCTN_datashare) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	id		
Arm	arm	Aspirin | Placebo	
Invasive Disease-Free Survival (iDFS) Time (months)	dfsmos		
Invasive Disease-Free Survival (iDFS) Status	dfs_stat	0 = Censored | 1 = Event	
Follow-Up Time (months)	fumos		
Participant vital status	fu_stat	Alive | Dead	
Breast Cancer-Related Death	breastrelated_dth	No | Yes	
HR status	hrstat_full	Negative | Positive and <=18 months since diagnosis | Positive and > 18 months since diagnosis	
BMI	bmi	Greater than or equal to 30 kg/m2 | Less than 30 kg/m2	

LABEL	NAME	ELEMENTS	COMMENTS
Stage	stage2	Stage II | Stage III	
Invasive Disease-Free Survival (iDFS) Event Type	dfs_type2	Death | Invasive Prog:Both | Invasive Prog:Distant | Invasive Prog:Local | New Primary	
Cycle 2 Patient Compliance	compliant12	No | Yes	At 12 months
Cycle 4 Patient Compliance	compliant24	No | Yes	At 24 months
Cycle 2 off-protocol use of NSAIDs	badnsaid12	No | Yes	At 12 months
Cycle 4 off-protocol use of NSAIDs	badnsaid24	No | Yes	At 24 months
Age (years)	age		
Age (years)	agecat	<40 | 40 - <50 | 50 - <60 | 60+	
BMI (kg/m2, at randomization)	bmibl		
Race	RACE_CAT_TXT	American Indian or Alaska Native | Asian | Black or African American | Native Hawaiian or other Pacific Islander | Not Reported | Unknown | White	
Ethnicity	ETHN_GRP_CAT_TXT	Hispanic or Latino | Not Hispanic or Latino | Not reported | Unknown	
Sex	PERSON_Sex	Female | Male	
End of Treatment Reason	endatrsn3	Adverse Event | Lost to Follow-up | On Study at time of Closure | Other | Patient Withdrew | Recurrence/Death	
Received Neoadjuvant or Adjuvant Chemo	prichemo	No | Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Time Since Diagnosis (months)	primdiagmos		At enrollment
Time on Treatment (months)	trtmos		
Menopausal Status	meno_grp	N/A Male Patient | Postmenopausal | Premenopausal	
Path Node Status	nstage	pN0 | pN1+ | Unknown/Missing	
Pathologic N Stage	max_nstage	pN0 | pN0(i-) | pN0(i+) | pN1 | pN1mi | pN2 | pN3 | pNX	
Race	mrace2	American Indian or Alaskan Native | Asian | Black or African American | More than one race | Native Hawaiian or Pacific Islander | Unknown/Not reported | White	
Location of New Primary	newprmloc1	Acute Lymphoblastic Leukemia (ALL) | Acute Myelogenous Leukemia | Colon | Invasive contralateral breast | Lung | Other | Ovary | Thyroid | Uterus	
5 Years Since Primary Diagnosis	prm5yr	No <5 years since prm | Yes >=5 years since prm	
Dose Modified to 100mg?	dose_mod	No | Yes	
AE Eligible	AE_eligible	0 = No| 1 = Yes	Included in AE analyses