

Information on the Aspirin for Breast Cancer (ABC) Clinical Trial

We are recruiting 2,936 women and men nationwide between the ages of 18 -70 diagnosed with node positive breast cancer in the past year, whose cancer has not recurred.

The purpose of this study is to determine if aspirin can prevent a recurrence of breast cancer or prevent the spread of breast cancer (metastatic breast cancer). Recent studies around the world have linked aspirin with a lower risk of death from cancer. This ABC Trial is the first U.S. study to test whether aspirin will keep breast cancer from recurring and reduce death from breast cancer.

What is expected of me?

You will be randomized (selected by chance) into one of two groups to take either 300 mg aspirin (regular strength) or a placebo (a tablet that looks like the study drug but contains no medication) everyday as provided by the trial. Neither you nor your provider will know which group you are in. At the time of enrollment, you will be asked to give blood, urine and access to your tumor samples if available. Blood and urine samples will be collected again in two years. A few survey questions on your general health and lifestyle will be collected at those time points. You will have a physical exam every 6 months and meet with a study doctor at your location.

Risks and benefits

If you are assigned to aspirin, you may be at increased risk of bleeding, including from the stomach or nose. However serious bleeding due to aspirin is rare. The most common and serious risks are described in the study consent form.

We do not know if aspirin will reduce your risk of breast cancer coming back. However, studies have shown aspirin can help prevent heart attacks and strokes in some people. The results of this study may help future breast cancer patients.

Patient protections

Participation is voluntary and you are free to leave any time. All data will be confidential and no individual's information will be released. Only group data will be published.

Who is running this trial?

The ABC Trial is funded by the U.S. Department of Defense Breast Cancer Research Program and the National Cancer Institute (NCI). Dana-Farber Cancer Institute and Brigham and Women's Hospital are conducting this study in cooperation with the Alliance for Clinical Trials in Oncology, which is a national clinical trials network sponsored by the National Cancer Institute (NCI). Patient advocates helped to develop this study and are active advisors.

More complete information is available at www.abctrial.org.