NCI Community Oncology Research Program – Kansas City (NCORP-KC)

Study Title for Study Participants: Aspirin for Breast Cancer Study (ABC study)

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 HER2 negative breast cancer: the ABC trial

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute, and is funded by the United States Department of Defense. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

What is the usual approach to my breast cancer?

You are being asked to take part in this research study because you have a history of node positive or high risk node negative breast cancer. People who are not in a study who have breast cancer are usually treated with surgery, chemotherapy, radiation, and/or medication that blocks estrogen if hormone receptor positive. The type of medication and/or chemotherapy depends upon the type of breast cancer. Aspirin is not currently part of usual care to prevent breast cancer recurrence.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above.
- You may choose to take part in a different study, if one is available.
- You may choose no treatment, but you may want to receive comfort care to relieve symptoms.

Why is this study being done?

The purpose of this study is to compare any good and bad effects of using aspirin after someone has completed the usual chemotherapy, surgery and/or radiation therapy for breast cancer. Some studies have suggested that aspirin may lower the risk of breast cancer coming back, but others have not, so we do not know if aspirin will help decrease breast cancer recurrence. This study will evaluate whether patients taking aspirin once per day will have a lower rate of cancer recurrence than patients taking a placebo. A placebo is a tablet that looks like the study drug (aspirin), but contains no medication. This is explained further in the section under the section titled "What are the Study Groups."

Aspirin is approved by the Federal Drug Administration (FDA) of the United States, but is not approved for the purpose of lowering the risk of breast cancer coming back or improving survival.

As part of this study you will be asked to complete five brief questionnaires, before starting the study drug, and after two years of taking the study drug. The information from these questionnaires will be used for future studies to evaluate any lifestyle factors that may be related to inflammation. It will take about 15-30 minutes to complete all of the questionnaires.

There will be about 2936 women and men taking part in this study.

What are the study groups?

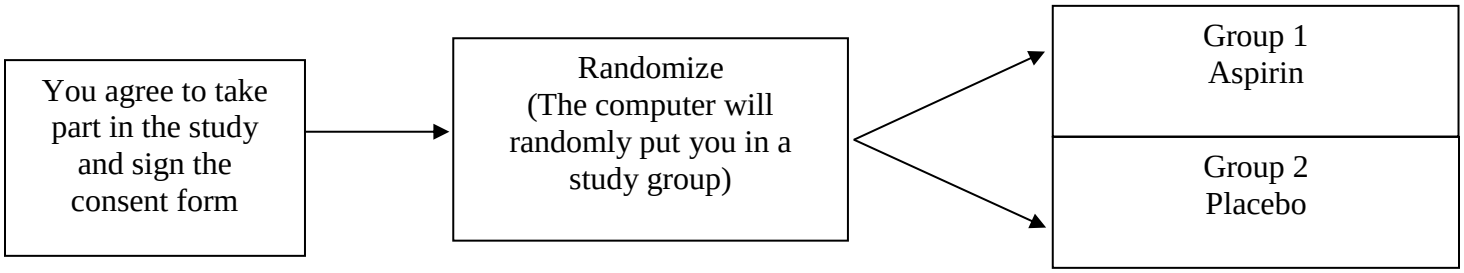
This study has two study groups. Group 1 will receive the study drug, aspirin at 300 mg per day. Group 2 will receive a placebo, a pill that looks like the study drug, but contains no medication. People who were recommended hormonal therapy will continue their hormonal therapy as directed.

A computer will by chance assign you to one of the treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the other. Neither you nor your doctor can choose the group that you will be in. You will have a 50% chance of being placed in the group receiving aspirin. Neither you nor your doctor will know which group you are assigned to. Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.

You will take one (1) aspirin or placebo tablet every day with food, or a full glass of water to help lessen stomach upset. The tablets should NOT be crushed.

If you decide to participate in this study you should not take additional aspirin or any nonsteroidal anti-inflammatory medications while you are in this study. Your study doctor will talk to you about what other medications you should not take while you are taking the study treatment.

If you choose to take part in the study, you will need to meet with your study doctor every six months to review any side effects and also to see if you are taking the study drug as directed.



No matter which group you are assigned to, you will be given a Medication Log to record the date, time and number of tablets that you take each day. You will be asked to bring the Medication Log to each study visit.

How long will I be in this study?

You will receive the study drugs for a maximum of 5 years. After you finish the study drugs, your doctor will continue to watch you for side effects and follow your condition for another 5 years.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- Aspirin may not be better, and could possibly be worse, than the usual approach for your cancer.
- If you are assigned to aspirin, there may be an increased risk of bleeding, including bleeding from the stomach or nose bleeding. Serious bleeding due to aspirin is rare.

There is also a risk that you could have side effects from the aspirin/placebo. These risks are described on the next page.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible side effects of aspirin/placebo

Possible Side Effects of Aspirin

COMMON, SOME MAY BE SERIOUS In 100 people receiving aspirin, more than 20 and up to 100 may have:
• Bruising • Decrease in the ability of platelets to clot

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving aspirin, from 4 to 20 may have:
• Irritation of the stomach or intestines • Ulcer of stomach or intestines • Bleeding from the stomach or intestines • Bleeding under the skin or more bleeding than usual from minor cuts can be expected. • Excess stomach acid • Feel like throwing up • Heartburn • Decreased red blood cells • Headache • Rash • Allergic reaction • Indigestion • Decreased appetite

RARE, AND SERIOUS In 100 people receiving aspirin, 3 or fewer may have:
• Narrowing or spasm of airways or wheezing • Reaction due to allergy • Complications of pregnancy • Seizures • Inflammation of liver or kidney • Impaired kidney function • Severe skin reactions • Ringing in ear • Serious bleeding • Bleeding in or around brain • Ulcers of gastrointestinal system that may perforate • Swelling of liver and brain (Reye's Syndrome)

Let your study doctor know of any question you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You and a member of the study team will discuss the potential risks of taking the study treatment while pregnant. They will help you decide whether or not you should use contraception while participating in this study. If you become pregnant while on this study, you should discuss with your study doctor whether or not you should stop the study treatment.

Appropriate methods of birth control include abstinence, oral contraceptives, implantable hormonal contraceptives or double barrier method (diaphragm plus condom).

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if aspirin will lower the risk of breast cancer coming back. However, studies have shown that aspirin can help prevent heart attacks and strokes in some people who are at risk for these events. This study will help researchers learn things that may help people with breast cancer in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

The aspirin and placebo will be supplied by Bayer, the manufacturer, at no charge while you take part in this study. The cost of getting the aspirin and placebo ready and giving it to you is also provided at no charge.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for study related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.
There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, Alliance for Clinical Trials in Oncology and Bayer, the drug company supporting this study.
- Other organizations from the National Clinical Trials Network that take part in this study
- The United States Department of Defense, that has provided funding for this study.
- The Dana Farber Cancer Institute.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say "no" to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this study, the study doctor for the main study would like to collect some breast cancer tissue from your previous breast biopsy or surgery, for future research. A new biopsy or surgery will not be required.
In addition to the breast cancer tissue, we are requesting an extra blood sample and a urine sample that will be collected before starting the study drug, and after two years of taking the study drug, for future studies.

If you choose to take part, the researchers will ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by the Alliance and supported by the National Cancer Institute and the Department of Defense which are helping to fund the study. If you would need to have samples returned to your study doctor for your care, your study doctor may request in writing for the specimens to be returned.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) If you agree to provide blood samples, samples of your urine and a sample of your cancer tissue, about 1 tablespoons of blood will be collected from a vein in your arm, and about 1 ½ tablespoons of urine will be collected before starting the study drug, and after two years of taking the study drug at the corresponding study visit. The sample from the tissue that was collected at the time of your surgery will be sent to the Biobank, a new biopsy or surgery will not be required.
2) Your samples and some related health information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you. Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
4) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
3) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
4) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and Alliance staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom the Alliance sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option (*include only applicable questions)*:

SAMPLES FOR FUTURE RESEARCH STUDIES:

1) My samples and related information may be kept in a Biobank for use in future health research.

YES NO

2) I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. this may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes.'

Participant's signature_____

Date of signature_____

(The following signature and date lines for the person(s) conducting the discussion may be included at the discretion of the study sponsor.)

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____