Aspirin for Prevention of Venous Thromboembolism Among Ovarian Cancer Patients Receiving Neoadjuvant Chemotherapy

NCT04352439

Document last approved by IRB: 06/01/2021

Form
M0345

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
PI: Brittany Davidson, MD

Aspirin for Prevention of Venous Thromboembolism Among Ovarian Cancer Patients Receiving Neoadjuvant Chemotherapy

CONCISE SUMMARY

We have found that nearly 8 out of every 100 women get a blood clot in the legs or the lungs while receiving chemotherapy for ovarian cancer prior to surgery. These blood clots can sometimes be dangerous. The purpose of this research study is to find out if taking a daily baby aspirin while receiving chemotherapy prior to surgery decreases your chance of getting a blood clot.

If you choose to enroll in this study, you will be instructed to take a baby aspirin every day while you are receiving chemotherapy before your surgery. We will continue to monitor your labs (platelet count, white blood cells) as we usually would. Your decision to enroll in this study will not change your cancer treatment plan.

There are risks to this study that are described in this document. Some risks include: upset stomach, medication reaction, and a higher risk of bleeding. There are also risks when you develop a blood clot.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have ovarian cancer and you will be receiving chemotherapy treatment prior to surgery ("neoadjuvant chemotherapy"). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Brittany Davidson and her colleagues are conducting this study and it is being funded by the Duke University Department of Obstetrics and Gynecology and the Division of Gynecologic Oncology.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, ***Dr. Davidson*** will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

IRB REFERENCE DATE: 06/01/2021
IRB EXPIRATION DATE: 06/17/2022

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WHY IS THIS STUDY BEING DONE?

We are performing this study to determine if taking a baby aspirin daily while receiving neoadjuvant chemotherapy for ovarian cancer decreases your chance of getting a blood clot in your legs or your lungs. We have found that these blood clots occur in nearly 8 out of every 100 women who are receiving chemotherapy for ovarian cancer prior to surgery. Blood clots can sometimes be dangerous and require you to be hospitalized. In addition, having a blood clot can cause delays in your chemotherapy treatment or your surgery. At present, aspirin is approved by the FDA for many conditions, but not specifically for the prevention of blood clots in women who are receiving chemotherapy for ovarian cancer prior to surgery. It is used frequently for this purpose in other patients who are at high risk for blood clot (for example, after hip surgery).

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 120 people will take part in this study: 60 from Duke Gynecologic Oncology Clinics and an additional 60 from Sarasota Memorial Health Care System.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form.

You will be given a supply of baby aspirin (81 mg) to take daily starting no later than the end of the day of your second cycle of chemotherapy until the day of your surgery. Most study participants will start taking their medication the first day of their first cycle. You will take one tablet daily unless otherwise advised by your doctor. You will continue to have all other aspects of routine care, including physical examination, clinic visits, and labs. Enrollment in this study will not change the cancer treatment plan that you make with your provider. We will also ask that you fill out a “medication adherence diary” where you will note whether or not you take the aspirin each day. We ask that you continue to take your baby aspirin until the day of your surgery unless otherwise instructed by your doctor. If one of your blood cell counts called platelets decreases below a certain value, your provider may ask that you stop taking your aspirin until your platelets increase again. We will document whether or not you experience a blood clot during your chemotherapy course. If you do get a blood clot, you will be treated with a blood thinner.

You may decide at any time during your clinic visit to withdraw from the study. Withdrawing from the study will not result in any changes in your care or your relationship with your provider or the care that you receive.

If you decide not to sign the consent form, you will continue to receive the indicated care, but it will not be as part of this study.

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HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will be for the duration of your neoadjuvant chemotherapy treatment through your surgery, approximately 6 to 9 months depending on the number of treatment cycles you receive.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

Being involved in this study, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with your study doctor and your regular health provider if you choose.

Aspirin may cause some, all, or none of the side-effects listed below.

More likely:

- Nausea
- Stomach pain
- Gastrointestinal ulcers

Less Likely:

- Bleeding
- Low platelet count
- Ringing in your ears
- Difficulty breathing
- Allergic reaction

There is a risk that you could have an allergic ("hypersensitivity") reaction to taking aspirin which will cause you to feel short of breath and can also include ringing in your ears and polyps in your nose. If you have had bariatric surgery, your doctor may recommend that you do not participate in this study. In addition, your doctor will review your medication list to make sure you are not taking another drug in the "antiplatelet" class (for example, if you've previously had a stent placed in your heart) or on another form of blood thinner.

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For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you but this cannot be guaranteed. Our hope is that taking a daily baby aspirin will lower your chance of having a blood clot while you are receiving chemotherapy. We hope that in the future the information learned from this study will benefit other people with your condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests and/or procedures performed (such as labs to monitor your platelet count). Some of these tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

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While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Brittany Davidson. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

There will be no additional costs to you as a result of being in this study. The aspirin will be provided free of charge to you.

WHAT ABOUT COMPENSATION?

You will not be compensated for participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Brittany Davidson at (919) 684-

3765 during regular business hours and at (919) 970-1613 after hours and on weekends and holidays

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you verbally notify the study staff during your clinic visit.

In addition, you must return all unused study drug to Dr. Brittany Davidson or her staff.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Brittany Davidson at (919) 684-3765 during regular business hours and at (919) 970-1613 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Subject	Date	Time
Signature of Person Obtaining Consent	Date	Time