Official Title: A Phase II Trial Evaluating Feasibility and Quality of Life of Second Look Laparoscopy with Hyperthermic intraperitoneal chemotherapy (HIPEC) in Patients with Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma

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A Phase II Trial Evaluating Feasibility and Quality of Life of Second Look Laparoscopy with Hyperthermic intraperitoneal chemotherapy (HIPEC) in Patients with Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma
Informed Consent Form to Participate in Research
Laurel Berry, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see if it is possible to give a patient hyperthermic intraperitoneal chemotherapy (HIPEC) at the time of a Second Look Reassessment Surgery. You are invited to be in this study because you have advanced ovarian, fallopian tube, or primary peritoneal cancer that has been treated with surgery and chemotherapy, you have no clinical signs of disease. Your participation in this research will involve receiving a Second Look Reassessment Surgery followed by hyperthermic intraperitoneal chemotherapy, it will include 7 visits, and last about one year.

Participation in this study will involve receiving HIPEC at the same time as your Second Look Reassessment Surgery. All research studies involve some risks. Common risks of HIPEC are bleeding and infection. Less common, but serious risks are the formation of blood clots in the legs, development of an opening between the intestines and the abdomen, and problems consuming enough calories after surgery. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include having treatment without participating in a study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Laurel Berry, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is [redacted] or [redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have ovarian, fallopian tube, or primary peritoneal cancer that has been treated with surgery and chemotherapy, you have no measurable signs of disease. Your participation is voluntary. Please take your time in making your decision as to whether or not

you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

Even though some people may have no visible signs of cancer after they have had surgery and chemotherapy, the cancer often returns. Patients often undergo a procedure called Second Look Reassessment Surgery or Second Look Surgery. This surgery allows doctors to look inside your body for signs of cancer. The purpose of this research study is to see if it is feasible to receive heated chemotherapy or heated intraperitoneal chemotherapy (HIPEC) inserted directly into your abdomen at the time of a Second Look Reassessment Surgery and to monitor any effects good or bad that this has on your health.

The chemotherapy drug used in this study is Carboplatin. The US Food and Drug Administration (FDA) has approved this drug for treating ovarian cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Ten people at Wake Forest Baptist Health will take part in this study. This study is being conducted exclusively at Wake Forest Baptist Health. No other sites are participating.

WHAT IS INVOLVED IN THE STUDY?

After your study doctor has answered all of your questions about this study and you have given written consent by signing this form, several tests will be done to be sure you are able to enter this study. Many of the tests will be the same as those you have had in the past to diagnose and treat your disease. Some of these same tests will also be done during the study to follow your progress.

At the pre-study visit, you will receive a physical exam and standard lab tests will be performed. Blood will be drawn from your arm for these tests. In addition, you will be asked to complete some questionnaires. These should take about 20 minutes to complete.

Additionally, while you are undergoing Second Look Reassessment Surgery, the physician will look in your abdomen for signs of cancer.

If you have visible signs of widespread cancer in your abdomen, you will not receive the HIPEC procedure and your continued participation in this study will consist of completing surveys regarding your cancer and allowing researchers to use information from your medical records for research.

If there are no visible signs of cancer in your abdomen or if there is a minimal amount of cancer, the doctor will perform a HIPEC procedure
For the HIPEC procedure, two catheters will be surgically inserted in your abdomen. A heated chemotherapy drug will be circulated through the catheters and into your abdomen for 90 minutes.

The study team will follow up with you after your surgery to see if you have had any adverse

effects from the surgery or medications. You will be monitored for adverse events for 3 months after your surgery.

Quality of Life Questionnaires (surveys)
You will be asked to complete quality of life questionnaires for research purposes. You will be asked to do this 3 times. These surveys will be given to you when you attend the follow up visits for your surgery. They should take about 10-15 minutes to complete.

Schedule

	Pre-Study [a]	Day of Surgery	Daily After the operation (while in hospital)	2 weeks	6 weeks	3 months	6 months
Informed consent	X						
Demographics	X						
Medical history	X						
Adverse event evaluation		X	X	X	X	X	
Physical exam	X	X	X	X	X	X	X
Pregnancy Test	X						
Blood work	X	X	X	X	X	X	X
CT of pelvis	X						
Quality of Life Questionnaires	X					X	X

How Long Will I Be in the Study?
You will be in the study for about one year.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any health or safety consequences

What Are the Risks of the Study?
Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

Risks Related to Intraperitoneal Carboplatin
Severity: Moderate
If any of the following side effects occur after receiving carboplatin through HIPEC, check with your doctor or nurse as soon as possible:

More common:
- Pain at the surgical site

Less common:
- Effects on the blood counts including a decrease in the following: hemoglobin possibly requiring blood transfusion; white blood cells which may increase the risk of infection that would require antibiotics; platelet count which may increase the risk of bleeding and require a platelet transfusion
- Thrombocytopenia, a condition in which there is a lower-than-normal number of platelets in the blood, may result in easy bruising and excessive bleeding Black, tarry stools
- blood in urine or stools
- cough or hoarseness, accompanied by fever or chills
- fever or chills
- lower back or side pain, accompanied by fever or chills
- numbness or tingling in fingers or toes
- painful or difficult urination, accompanied by fever or chills
- pinpoint red spots on skin
- skin rash or itching
- unusual bleeding or bruising
- unusual tiredness or weakness

Rare
- Blurred vision
- ringing in ears
- sores in mouth and on lips
- wheezing

Minor Side Effects
Some of the side effects that can occur with carboplatin may not need medical attention. As your body adjusts to the medicine, these side effects may go away. Your health care professional may also be able to tell you about ways to reduce or prevent some of these side effects. If any of the following side effects continue, are bothersome or if you have any questions about them, check with your health care professional:

More common:
- Nausea and vomiting
- unusual tiredness or weakness

Less common:
- Constipation or diarrhea
- loss of appetite

This medicine may cause a temporary loss of hair in some people. After treatment with carboplatin has ended, normal hair growth should return.

Risks of HIPEC
The risks of the HIPEC procedure include infection, bleeding with need for blood transfusion, injury to surrounding structures, which may cause the need for additional surgery to repair such injury, blood clots, prolonged hospitalization, and death.

Risks of Questionnaires (surveys)
In this study you will be asked how you are feeling and how your cancer and treatment are affecting your life. These feelings may become stronger when you are answering these questions.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Reproductive Risks and other Issues to Participating in Research
Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You may or may not receive direct benefit from taking part in this research study. HIPEC at the time of your surgery may delay the growth of cancer. We also hope the information learned from this study will benefit other people in the future.

Based on experience with HIPEC in clinical care, researchers believe it may be of benefit to subjects with your condition. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?
You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- You could participate in other clinical trials.

- You could choose to monitor your cancer by imaging scans prescribed by your regular physician
- You may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

WHAT ARE THE COSTS?

You or your insurance company will be billed for the all of the costs of treating your cancer while in this study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of HIPEC during Second Look Laparoscopic Reassessment Surgery; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

WILL YOU BE PAID FOR PARTICIPATING?

You will not receive payment for taking part in this study; parking will be validated for study related visits.

WHO IS SPONSORING THIS STUDY?

This study is sponsored by Wake Forest Baptist Comprehensive Cancer Center. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Laurel Berry at [redacted] or 3[redacted] (24 hour number).

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** name, medical record number, health information from your clinic visits, test results, medicines you are taking, Quality of Life assessments and response to therapies.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

You can tell Dr. Laurel Berry that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Laurel Berry, MD

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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

Laboratory test results and other clinically relevant medical reports created as a result of your

participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Berry at [redacted] (24 hour number).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm