Official Title: A Phase II Trial Comparing Quality of Life After HIPEC in Patients With Stage IIIC and IV Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma
NCT03188432
IRB-Approved Date: 3/30/23

A Phase II Trial Comparing Quality of Life After HIPEC in Patients with Stage IIIC and IV Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma – CCCWFU 83216

Informed Consent Form to Participate in Research
Michael G. Kelly, MD; Principal Investigator

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 stage IIIC or IV ovarian cancer, fallopian tube or primary peritoneal cancer, you have completed standard neoadjuvant chemotherapy, and you will now require surgery to remove the tumors. 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?

The purpose of this research study is to assess the quality of life in patients that have a procedure called HIPEC to treat their cancer. HIPEC stands for hyperthermic intraperitoneal chemotherapy. In HIPEC, the chemotherapy is warmed before being used. This is believed to help the chemotherapy drugs get into the cancer cells better than and minimize the toxicity of the drugs on normal cells. HIPEC will be performed immediately after surgery to remove the tumors. This is done to help kill any cancer cells left over after surgery. The study is aimed assessing the quality of life of patients who receive the HIPEC treatment for their cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Fifty (50) people at 1 research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

In this study you will be screened for us to see if you are eligible for the study. If so, you will be asked to sign this informed consent form and you will give blood, have a medical history taken, vital signs, performance status determined and you will have a computed tomography (CT) scan of your abdomen.

HIPEC

You will have received at least 3, but no more than 8 cycles of chemotherapy administered through your vein prior to your enrollment onto this study. After enrollment onto this study, you

will then have surgery to remove the remaining portions of your cancer. Immediately after removal of the cancers and during surgery, you will have the HIPEC procedure performed.

HIPEC stands for "hyperthermic intraperitoneal chemotherapy." For the HIPEC treatment you will receive chemotherapy (a drug called carboplatin) that is heated, injected *directly into your abdominal cavity,* and allowed to circulate inside your abdomen during surgery. After a certain time period (usually 90 minutes) the chemotherapy will be removed.

Carboplatin is FDA approved for use in ovarian cancer. The dose of carboplatin chosen for administration with HIPEC in this study is 800mg/m2, and this dose was previously established in another study at this institution.

You will be asked to fill out 4 quality of life surveys: once at your pre-study assessment visit, after your surgery at week 6, month 3, and month 6. Also, you will have a CT scan of your abdomen at the beginning of the study, then at 3, 6, and 12 months after your surgery is completed.

If you take part in this study, you will have the following tests and procedures:

Blood draws
You will have approximately 3 teaspoons of blood withdrawn from a vein *4 times throughout the study*. The total amount of blood withdrawn during the study will be approximately *12 teaspoons*. These draws occur as a part of your standard of care. This means they are a part of your normal care and would happen even if you were not in the study.

HIPEC
HIPEC is a procedure where, during surgery, warmed chemotherapy is delivered directly to the site of the cancer. This is also considered a standard of care chemotherapy procedure in addition to the neoadjuvant chemotherapy you had completed prior to being in this study.

Surgery
Surgery to remove the remaining portions of tumor is a part of standard of care for your cancer.

CT Scans
CT scans will be performed as a part of your standard of care. There will be up to 4 of these throughout the time period for this study.

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 4 times.

A Physical Exam
A physical exam will be performed as a part of your standard of care. You will have 5 of these throughout the time period for this study – one at your pre-study visit and one at each outpatient follow-up visit (6 weeks, 3 months, 6 months, 12 months.)

How Long Will I Be in the Study?
You will be in the study for about 12 months.

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 potential 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. Most of the procedures (as listed above) are part of your standard of care and the risks will be explained to you by your doctor. However, the risks for those procedures in which the results are also being used for research are also described below. Risks and side effects related to the procedures we are studying include:

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

Risks of Surgery
The risks of surgery include infection, bleeding with need for blood transfusion, injury to surrounding structures with need to perform additional surgery to repair such injury, thromboembolism, prolonged hospitalization and death.

Risks of Surveys
You will be filling out surveys during this study. While filling these out, you may experience certain emotions more intensely than usual and/or become more aware of your cancer symptoms than if you did not complete the surveys.

Risks of CT Scans
You will be exposed to radiation from the CT-scan device as part of your standard cancer care during your time on this research study. There is always a slight chance of cancer from radiation. However, the benefit of an accurate diagnosis far outweighs the risk. The effective radiation dose from this procedure is about the same as the average person receives from background radiation in three years.

To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

Risks Related to Intraperitoneal Carboplatin
As well as its needed effects, carboplatin may cause unwanted side effects that require medical attention.

Severity: Moderate
If any of the following side effects occur after being injected with carboplatin, check with your doctor or nurse as soon as possible:

More common:
- Pain at place of injection **Less common:**
- 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.

Reproductive Risks and other Issues to Participating in Research

Due to 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, intrauterine device (IUD), 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 cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

Risks Related to Providing Confidential or Private Information

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 side effects 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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be the reduction of your cancer. However, 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:

Cytoreductive surgery and a combination of intravenous and/or intraperitoneal chemotherapy or HIPEC; hence you may receive these therapies even if you weren't on the study.

WHAT ARE THE COSTS?

There are no costs directly associated with your taking part in this study. All study-related procedures, including research staff time and the administration of the questionnaires, will be paid for by the study sponsor.

Costs for your standard medical care, which would happen regardless of study participation, will be your own financial responsibility. This includes (but is not limited to) the office visits, physical exams, vital signs, surgery, HIPEC procedure, blood labs, and all the CT scans.

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.

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 research study. 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.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by *Wake Forest University Health Science*. The sponsor is providing money or other support to help conduct this study. The researchers do not, however, 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 Michael Kelly, M.D. at [redacted] or [redacted] (clinic and after-hours 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**:**

- Your health history
- How you respond to study procedures
- Laboratory and other tests
- Physical examinations

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), 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.

1) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

2) Representatives from government agencies such as the US Food and Drug Administration (FDA)

3) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

4) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health

Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time, any research information not already in your medical record will either be destroyed or de-identified. Any research information entered directly into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Michael Kelly, M.D. 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:

Michael G. Kelly, 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 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 for any reason the Principal Investigator feels may be necessary for your care in relation to the study.

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, Michael G. Kelly, MD, [redacted] or [redacted] (clinic and after-hours 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