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

TITLE OF RESEARCH PROJECT: GOG-0238: A RANDOMIZED TRIAL OF PELVIC IRRADIATION WITH OR WITHOUT CONCURRENT WEEKLY CISPLATIN IN PATIENTS WITH PELVIC-ONLY RECURRENCE OF CARCINOMA OF THE UTERINE CORPUS
NCI Version Date: October 9, 2014

PRINCIPAL INVESTIGATOR:

GENERAL

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You have also been told that you have the option not to participate. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, ask your study doctor for more explanation.

This study is being carried out under the sponsorship of the Gynecologic Oncology Group (GOG), an organization dedicated to clinical research in the field of gynecologic cancer. The GOG is funded by the Federal Government through the National Cancer Institute (NCI).

You are being asked to take part in this study because you have endometrial cancer that has come back (recurred) after you have been treated with surgery and possibly chemotherapy. Your cancer does not appear to have spread beyond your pelvis.

WHY IS THIS STUDY BEING DONE?

The main purpose of this study is to compare radiation therapy in combination with weekly treatment with the chemotherapy drug cisplatin to the standard treatment for this type of cancer. The standard treatment for patients with your type of cancer is radiation therapy alone. Radiation therapy is a cancer treatment that uses radiation beams from outside your body, or radioactive seeds or pellets placed directly into the tissue to kill cancer cells. Radiation therapy alone has not been very effective in treating large tumors that recur (come back) in the pelvis, lymph nodes or vagina. Radiation therapy in combination with weekly treatment with the chemotherapy drug cisplatin has been found to be very effective in treating patients with advanced cervical cancers. Another purpose of the study is to evaluate the side effects of the combination of radiation therapy and cisplatin.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 200 patients will be included in the study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study

You will have the following exams, tests, and procedures to find out if you can be in the study. These exams, tests, or procedures may be done as part of your routine care, even if you do not join the study. If you have had some of them done recently, they may not need to be repeated. This will be up to your study doctor.

- History and physical examination which may include pelvic examination
- Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function
- Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required
- CT scan of the abdomen and pelvis to measure detectable tumor
- EKG (Electrocardiogram) or electrical tracing of your heart beat

The following tests will be performed if you doctor decides they are medically needed, which are part of the standard care.

- Biopsy of your tumor (surgical removal of a piece of your tumor)
- Barium Enema (a picture of the colon after barium is inserted through your rectum)
- Proctoscopy (a lighted instrument inserted into your rectum)
- Cystoscopy (a lighted instrument inserted into your bladder)
- Renal Ultrasound (computerized picture of your kidneys)
- Audiogram (hearing test)

During the study:

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

- Weekly history and physical examination which may include pelvic examination
- Weekly blood tests to measure blood counts, blood mineral levels, and kidney function
- One or more of the additional studies listed above may be performed if clinically indicated (which would be performed independently whether on the study or not)

You will need these tests and procedures that are part of regular cancer care. They are being done more often because you are in this study.

- Evaluation of side effects you may experience from the study treatment

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are in Group 1 (called Regimen I), your treatment will consist of:

- External Beam Radiation Treatment (radiation treatment from a machine):
  You will receive radiation 5 days a week (Monday –Friday) for 5 weeks.
- Brachytherapy (additional radiation treatment): Following the completion of the external beam radiation therapy, you will receive additional radiation, called brachytherapy. Brachytherapy, also called internal radiation, is a type of radiation therapy where radioactive materials are placed in directly within or near the tumor for a limited period of time. You may either receive low dose rate brachytherapy (LDR) or high dose rate brachytherapy (HDR). The radioactive materials are either placed inside the vagina (intracavitary brachytherapy) or inserted into the tumor itself (interstitial brachytherapy) using a special needle in the operating room. LDR requires hospitalization because the radioactive materials will be placed in your body for an extended period of time, no greater than 3-5 days. The implant will be removed prior to your release as well as all of the radiation material. HDR can be done in a series of outpatient procedures, as the doses of radiation can be inserted in your body for a shorter period of time then removed.
- Additional External Beam Radiation Treatment (Radiation treatment from a machine):
  If you are not able to have brachytherapy, you will receive additional external beam radiation therapy 5 days a week (Monday-Friday) for 2 weeks.

If you are in Group 2 (called Regimen II), your treatment will consist of:

- External Beam Radiation Treatment (radiation treatment from a machine):
  You will receive radiation 5 days a week (Monday –Friday) for 5 weeks.
- Brachytherapy (additional radiation treatment): Following the completion of the external beam radiation therapy, you will receive additional radiation, called brachytherapy. Brachytherapy, also called internal radiation, is a type of radiation therapy where radioactive materials are placed in directly within or near the tumor for a limited period of time. You may either receive low dose rate brachytherapy (LDR) or high dose rate brachytherapy (HDR). The radioactive materials are either placed inside the vagina (intracavitary brachytherapy) or inserted into the tumor itself (interstitial brachytherapy) using a special needle in the operating room. LDR requires hospitalization because the radioactive materials will be placed in your body for an extended period of time, no greater than 3-5 days. The implant will be removed prior to your release as well as all of the radiation material. HDR can be done in a series of outpatient procedures, as the doses of radiation can be inserted in your body for a shorter period of time then removed.
- Additional External Beam Radiation Treatment (Radiation treatment from a machine):

If you are not able to have brachytherapy, you will receive additional external beam radiation therapy 5 days a week (Monday-Friday) for 2 weeks.

- Cisplatin
  You will receive cisplatin (chemotherapy) 5 times through a vein (IV) over one to two hours, beginning the first day of radiation therapy and continuing once a week for 5 weeks. You will receive cisplatin approximately four hours before your radiation treatment.
  Prior to and after the administration of the chemotherapy, you will be given intravenous medication (into the vein) and oral (by mouth) medication to prevent you from developing nausea and vomiting.

After your treatments are completed:

To monitor your well-being and the status of your cancer, you will undergo these tests and procedures that are part of regular cancer care:

- History and physical examination which may include pelvic examination every three months for the first two years and then every six months for the next three years
- Blood tests to measure blood mineral levels, and check liver and kidney function every three months for the first two years and then every six months for the next three years
- Blood tests to check liver function every month for the first three months after completing treatment, and then every three months for the first two years and then every six months for the next three years
- Evaluation of side effects you may experience from the study treatment every three months for the first three months after complaining treatment, and then every six months for the next three years
- Chest imaging (chest x-ray) will be done at the end of treatment and then every six months for a minimum of 5 years
- CT scan of the abdomen and pelvis to measure detectable tumor will be done at the end of treatment and then every six months for a minimum of 5 years
- Blood tests to measure blood counts if your doctor feels it is needed
- Pap Smear if your doctor feels it is needed
- Audiogram if your doctor feels it is needed

Study Chart

If you are on **Regimen I,** you will receive radiation therapy everyday (except weekends). This 7-day period of time is called a cycle. The cycle will be repeated 4 more times for a total of 5 cycles (5 weeks). During Week 6 or 7 you will receive brachytherapy which may require you to stay in the hospital for approximately 3-5 days. Each cycle is numbered in order. The chart below shows what will happen to you during Cycle 1 and future treatment cycles as explained previously. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Regimen I

Prior to start of treatment	• History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function • Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required • CT scan of the abdomen and pelvis to measure detectable tumor • EKG (Electrocardiogram) or electrical tracing of your heart beat
Day 1- Cycle 1 Week 1	• Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Day 8- Cycle 2 Week 2	• Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Day 15-Cycle 3 Week 3	• Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Day 22-Cycle 4 Week 4	• Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Day 29- Cycle 5 Week 5	• Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Week 6 or 7	• Brachytherapy: LDR will require you to stay in the hospital

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	approximately 3-5 days OR HDR which can be done over a series of outpatient visits OR • Additional external beam radiation treatment for 2 weeks • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function • Evaluation of side effects you may experience from the study treatment
After you have completed treatment	• History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function • Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required • CT scan of the abdomen and pelvis to measure detectable tumor • Evaluation of side effects you may experience from the study treatment
Follow-up visits every month for the first 3 months after the completion of treatment	• Evaluation of side effects you may experience from the study treatment • Blood tests to check liver function
Follow-up visits every 3 months from the completion of treatment for 2 years and then every 6 months for the next 3 years	• History and physical examination which may include pelvic examination • Blood tests to measure blood mineral levels, and check liver and kidney function • Blood tests to measure blood counts when clinically indicated • Evaluation of side effects you may experience from the study treatment
Follow-up visits every 6 months from the completion of treatment for 5 years	• Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required every six months and as clinically indicated • CT scan of the abdomen and pelvis to measure detectable tumor every six months
If you are removed from the study during treatment for any reason	• History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function • Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required

	• CT scan of the abdomen and pelvis to measure detectable tumor • Evaluation of side effects you may experience from the study treatment

If you are on **Regimen II** you will receive cisplatin once a week (preferably Mondays) and radiation therapy everyday (except weekends). This 7-day period of time is called a cycle. The cycle will be repeated 4 more times for a total of 5 cycles (5 weeks). During week 6 or 7 you will receive brachytherapy which may require you to stay in the hospital for approximately 3-5 days. Each cycle is numbered in order. The chart below shows what will happen to you during Cycle 1 and future treatment cycles as explained previously. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Regimen II

Prior to start of treatment	• History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function • Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required • CT scan of the abdomen and pelvis to measure detectable tumor • EKG (Electrocardiogram) or electrical tracing of your heart beat
Day 1- Cycle 1 Week 1	• IV Cisplatin • Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Day 8- Cycle 2 Week 2	• IV Cisplatin • Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Day 15-Cycle 3 Week 3	• IV Cisplatin • Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment

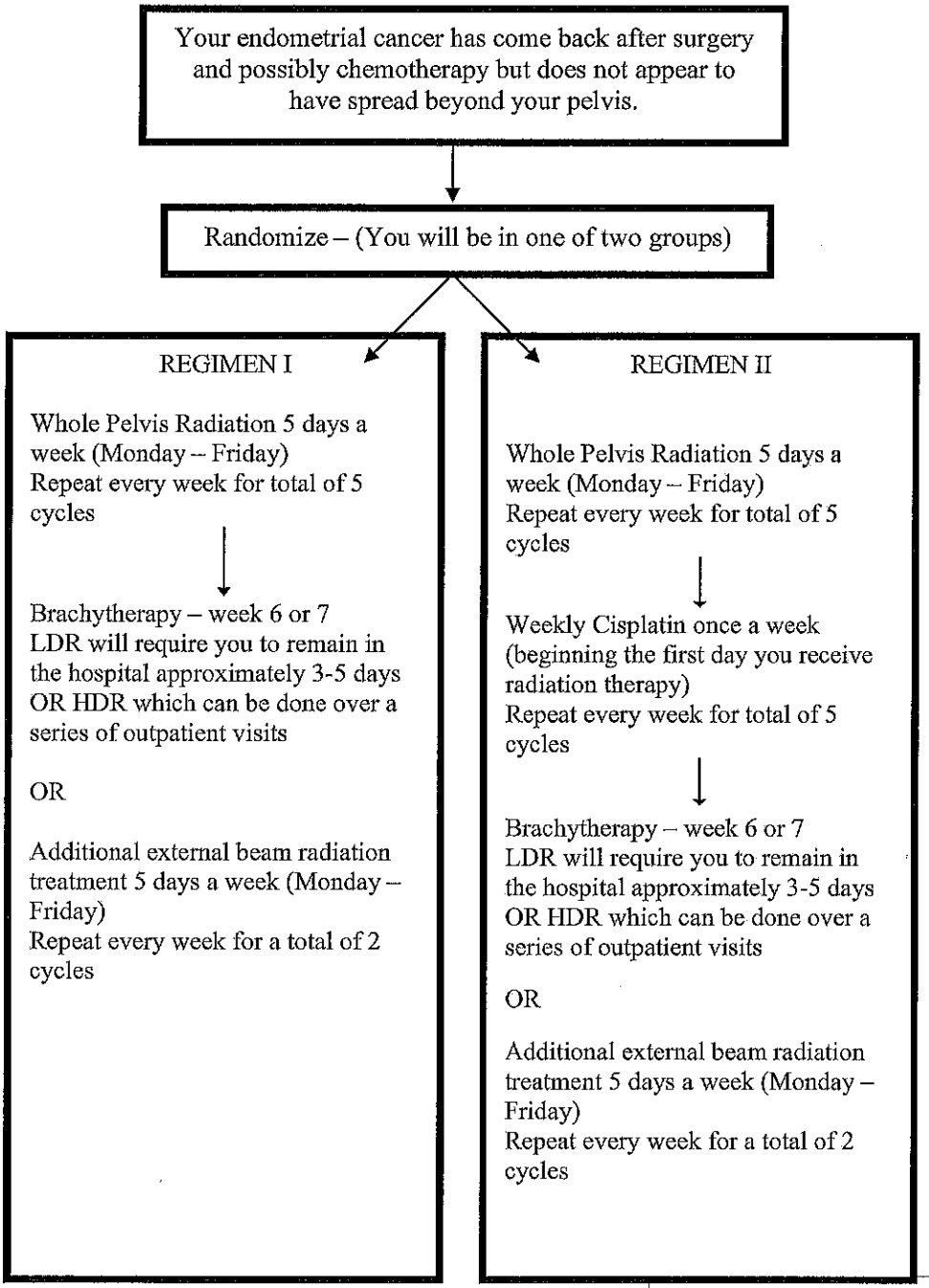
Day 22-Cycle 4 Week 4	• IV Cisplatin • Radiation Therapy x 5 days • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment

Day 29- Cycle 5 Week 5	• IV Cisplatin • Radiation Therapy x 5 days • History and physical examination which will include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
Week 6 or 7	• Brachytherapy: LDR will require you to stay in the hospital approximately 3-5 days OR HDR which can be done over a series of outpatient visits OR • Additional external beam radiation treatment for 2 weeks • History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check kidney function • Evaluation of side effects you may experience from the study treatment
After you have completed treatment	• History and physical examination which may include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function • Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required • CT scan of the abdomen and pelvis to measure detectable tumor • Evaluation of side effects you may experience from the study treatment
Follow-up visits every month for the first 3 months after the completion of treatment	• Evaluation of side effects you may experience from the study treatment • Blood tests to check liver function
Follow-up visits every 3 months from the	• History and physical examination which may include pelvic examination • Blood tests to measure blood mineral levels, and check liver and kidney

completion of treatment for 2 years and then every 6 months for the next 3 years	function • Blood tests to measure blood counts when clinically indicated • Evaluation of side effects you may experience from the study treatment
Follow-up visits every 6 months from the completion of treatment for 5 years	• Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required every six months and as clinically indicated • CT scan of the abdomen and pelvis to measure detectable tumor every six months
If you are removed from the study during treatment for any reason	• History and physical examination which will include pelvic examination • Blood tests to measure blood counts, blood mineral levels, and check liver and kidney function • Chest imaging (x-ray); if x-ray is abnormal a CT scan of the chest is required • CT scan of the abdomen and pelvis to measure detectable tumor • Evaluation of side effects you may experience from the study treatment

Study Plan

Another way to understand what will happen during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



HOW LONG WILL I BE IN THE STUDY?

If you are on **Regimen I,** you will receive radiation therapy for 5 weeks and then additional radiation brachytherapy treatment during Week 6 or 7, which takes approximately 3-5 days. If you are not able to have brachytherapy, you will receive additional external beam radiation therapy for 2 weeks. If you are on **Regimen II,** you will receive cisplatin and radiation therapy for 5 weeks with the additional radiation brachytherapy treatment during Week 6 or 7, which takes approximately 3- 5 days. If you are not able to have brachytherapy, you will receive additional external beam radiation therapy for 2 weeks. After you have completed treatment, you will be monitored for side effects and have blood tests to check your liver function every month for three months for the first two years and then every six months for the next three years.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the cisplatin and radiation therapy can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she thinks it is best for you; if you do not follow the study rules; or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the **cisplatin and receiving radiation therapy.** In some cases, side effects can be serious because they can be long lasting, may never go away, may result in hospitalization, or may be life-threatening.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to **Cisplatin** include those which are:

Likely:

- Fatigue
- Lowered white blood count may increase risk of infection
- Lowered red blood cells may lead to anemia, tiredness, or shortness of breath

- Lowered platelets may lead to an increase in bruising or bleeding
- Decrease in kidney function
- Loss of appetite and weight loss
- Diarrhea, constipation, nausea and vomiting, and abdominal pain
- Complete hair loss
- Numbness or tingling in fingers or toes
- Changes in taste
- Ringing in the ears and hearing loss
- Changes in electrolytes in the blood such as calcium, magnesium and potassium
- Medication for control of nausea, vomiting, diarrhea or constipation may be required and will be prescribed by your doctor
- Additional medication for low potassium or magnesium may be required and will be prescribed by your doctor

Less likely but serious:

- Allergic reactions
- Chills and fever with aches and pains
- Sores in mouth and throat (that can lead to difficulty swallowing and dehydration)
- Altered vision
- Skin irritation and swelling if the drug leaks from the vein into which it is being injected into the surrounding skin
- Abnormal liver function

Rare:

- Seizures
- Secondary cancers such as acute leukemia
- Kidney failure requiring dialysis
- Deafness
- Skin rash
- Abnormal heart function

Risks and side effects related to **External Radiation Therapy** include those which are:

Likely:

- Tanning or reddening of the skin which is exposed to the radiation beam
- Burning or pain during urination or defecation
- Nausea, vomiting, diarrhea, abdominal pain
- Fatigue
- Permanent pubic hair loss
- Lowered white blood count may increase risk of infection
- Lowered red blood cells may lead to anemia, tiredness, or shortness of breath

- Lowered platelets may lead to an increase in bruising or bleeding
- Medication for control of nausea, vomiting, diarrhea or constipation may be required and will be prescribed by your doctor
- Additional medication for low potassium or magnesium may be required and will be prescribed by your doctor

Less likely but serious:

- Damage to the small or large intestine, rectum, ureter, or bladder, which may require medication, hospitalization for management, or rarely a surgical procedure to repair.

Rare:

- Nerve damage which may cause numbness or weakness in the legs

Risks and side effects related to the **Brachytherapy** include those which are:

Likely:

- Pain
- Potential bleeding
- Fatigue
- Burning sensation

Rare:

- Potential risk for clots in your legs that may result in pulmonary embolism (clots that travel from your legs to your lungs), that could cause severe problems breathing and even death
- Severe bleeding
- Infections
- Severe damage to rectum and/or bladder that could result in a fistula (hole) between the rectum and the vagina or the bladder and the vagina. These complications may require an operation that could result in a permanent colostomy (a bag in the belly for the stools) or urinary diversion (a bag in the belly for the urine)

Risks and side effects related to **Blood Draw** include:

- Pain
- Bruising
- Lightheadedness
- Infection (on rare occasions)

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking pare in this study may or may not make your health better. While doctors hope that the combination of cisplatin and radiation therapy will be more useful against cancer compared to the

usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about using this combination of cisplatin and radiation therapy as a treatment for cancer. This information could help future cancer patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study which may include surgery, radiation and chemotherapy in varying combinations
- Taking part in another study
- Getting no treatment
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential, and GOG procedures may include removing your name and other identifying information from data collected during the Study, in order to protect your privacy. However, we cannot guarantee total confidentiality. Portions of your medical records will be sent to the GOG Administrative Office, the GOG Statistical and Data Center, and possibly to the GOG Tissue Bank, to be reviewed and analyzed by physicians and other Study personnel. Your records may be accessed by GOG representatives and by the NCI for research, quality assurance, and data analysis purposes. Your record may also be accessed by the Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.

In addition, your records may be reviewed by the Food and Drug Administration (FDA), or other agencies of the Department of Health and Human Services (DHHS) for research or regulatory purposes. Also, information from the Study may be given to government agencies in other countries where the study drug may be considered for approval.

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 study results. You can search this Web site at any time.

Under NCI policy, data from this Study may be provided to another researcher at some future time for use in an approved research project. If this occurs, the researcher must agree to keep individual patient information confidential.

When the research results are published or discussed in conferences, no information will be included that reveals your identity.

The National Institutes of Health (NIH) has issued GOG a Certificate of Confidentiality, which protects GOG from being forced to disclose personal information about you in response to a subpoena or other request in a federal or state legal proceeding.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate or withhold that information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study, including the cost of managing the side effects of therapy. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. You will be responsible for paying any deductibles, coinsurance, and co-payments as required under the terms of your insurance plan(s).

You will not be paid for taking part in this study. The institution receives payment which covers some but not all of the costs of the study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage . You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, _____ *[investigator's name(s)]*; if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number]*.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

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

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* at _____ *[telephone number]*.

For questions about your rights while taking part in this study, call the NCI Community Oncology Research Program – Kansas City Institutional Review Board (*a group of people who review the research to protect your rights*) at 913-948-5588.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

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.

SIGNATURE

I have been given a copy of all 17 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

_____
Printed Participant Name

_____
Participant Signature Date

_____
Printed Name of Person Obtaining Consent Date

_____
Signature of Person Obtaining Consent Date