EORTC Gynecological Cancer Group
EORTC Soft Tissue and Bone Sarcoma Group
EORTC 55116-62114
(EudraCT number 2012-002852-17)
(NCT01533207)

A Phase III Randomized Trial of Gemcitabine plus Docetaxel followed by Doxorubicin v. observation for uterus-limited, High Grade Uterine Leiomyosarcoma.

Patient information sheet and informed consent

<table>
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<tr>
<th>PIS/IC version</th>
<th>Date of PRC approval/notification</th>
<th>Amendment reference N°</th>
<th>Classification</th>
<th>Applicable for Protocol</th>
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<td>1.0</td>
<td>04 December 2012</td>
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<td>GOG-0277-April 25, 2012 and subsequent versions</td>
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<td>1.1</td>
<td>04 October 2013</td>
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<td>Administrative</td>
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TITLE OF RESEARCH PROJECT: A Phase III Randomized Trial of Gemcitabine plus Docetaxel followed by Doxorubicin versus Observation for Uterus-Limited, High-Grade Uterine Leiomyosarcoma

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, you can ask your study doctor for more explanation.

This trial is part of an International Rare Cancers Initiative (IRCI) cooperation between the following academic organizations: the European Organisation for Research and Treatment of Cancer (EORTC), the American Gynecologic Oncology Group of the National Cancer Institute (NCI-GOG) and the National Cancer Research network (NCRN) in United Kingdom.

This trial is proposed by NCI-GOG, an organization dedicated to clinical research in the field of gynecologic cancer. The GOG is funded by the US Federal Government through the National Cancer Institute (NCI).

This study is being carried out in Europe under the sponsorship of the European Organisation for Research and Treatment of Cancer (EORTC) which is a non-profit research organization.

You are being asked to take part in this study because you have a specific kind of uterine cancer; called a leiomyosarcoma that was found only in your uterus; and which has been completely removed by surgery.

WHY IS THIS STUDY BEING DONE?

The current standard management for patients with leiomyosarcoma of the uterus which has been completely removed by surgery is to follow patients closely to check if the leiomyosarcoma comes back. Many patients may remain without any evidence of the cancer coming back after having had surgery to take out the leiomyosarcoma. In some patients, however, the leiomyosarcoma does come back.

Currently when leiomyosarcoma comes back (recurs) the leiomyosarcoma may be treated with chemotherapy. There are several chemotherapy drugs that can shrink leiomyosarcoma tumors. These include the combination treatment of gemcitabine and docetaxel, and another drug called doxorubicin.

In this study, we are looking to see if giving chemotherapy with gemcitabine plus docetaxel, followed by doxorubicin, to patients whose leiomyosarcoma was found only in the uterus, decreases the chance that the leiomyosarcoma will come back (recur). In this study half the patients will be managed in the standard way, which is to follow them closely with CT scans, and see if the disease ever comes back. This will be called the “Standard Treatment Group or Group A.”

The other half of the patients will be treated with chemotherapy and also followed to see if the disease comes back. This will be the “Experimental Treatment Group or Group B.” We will learn whether or not the chemotherapy lowers the chance of the leiomyosarcoma coming back and whether or not the patients who are treated with chemotherapy live longer than the patients who are observed. Giving chemotherapy to patients with leiomyosarcoma of the uterus which has been completely removed by surgery is considered experimental.
This is a randomized trial. 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.

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

About 216 women will take part in this study.

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

**Before you begin the study**

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

- History and physical examination, which may include a pelvic examination.
- Blood tests to measure blood cell counts, blood mineral levels, and check liver and kidney function. This will require about 1 tablespoon of blood.
- ECHO or MUGA test to check your heart function.
- Electrocardiogram to check your heart electrical activity.
- CT scan of the chest, abdomen and pelvis or CT scan of the chest and an MRI of the abdomen and pelvis to make sure there is no evidence of cancer remaining after your surgery.
- Review of medications and supplements you are currently taking.

In order to confirm the initial diagnosis made by the pathologist in your hospital, either images or a very small piece of your tumor material may be reviewed by expert pathologists using microscopy or any other method. These experts may examine your tumor material that was taken when the diagnosis was made or during surgery/biopsy at any other point in time. These pathologists may not work in the hospital where you receive(d) protocol treatment, nor even in the same country. In case of discrepancy, your treating physician will be informed.

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will be assigned to either the standard treatment group of careful follow-up or to the experimental treatment group of chemotherapy.

If you are assigned to **Group A** (standard treatment group), this is what you will do:

**During the study**

You will need the following tests and procedures, as part of your regular cancer care:

- History and physical examination which may include a pelvic examination approximately 4 months after starting study.
- Blood tests to measure blood cell counts, blood mineral levels and check liver and kidney function approximately 4 months after starting study. This will require about 1 tablespoon of blood.
♦ Every 3-4 weeks for the first 6 months you will receive a telephone call from a nurse or doctor to ask if you are experiencing any side effects.

♦ CT scan of the chest, abdomen, and pelvis, or CT scan of the chest and MRI of the abdomen and pelvis approximately 4 months after starting study.

♦ Review of medications and supplements you are currently taking approximately 4 months after starting study.

If you are assigned to **Group B** (experimental treatment group), this is what you will do:

**During the study**

You will need the following tests and procedures as part of your regular cancer care:

♦ History and physical examination which may include a pelvic examination prior to each cycle of chemotherapy.

♦ Blood tests to measure blood counts (CBC). CBC will be done on or prior to the first day of each treatment, and again one week later, during the first 4 cycles of chemotherapy treatment (with gemcitabine and docetaxel). During the second 4 cycles of chemotherapy (with doxorubicin) the CBC will be done on or prior to the first day of treatment.

♦ Blood tests to check liver and kidney function prior to starting each cycle.

♦ CT scan of the chest, abdomen, and pelvis, or CT scan of the chest and MRI of the abdomen and pelvis approximately 4 months after starting study.

**Chemotherapy treatment: gemcitabine + docetaxel for 4 cycles**

♦ You will receive Gemcitabine intravenously by vein (IV) over about 90 minutes on Day 1.

♦ On Day 7 you will take dexamethasone by mouth twice a day for three days to prevent allergic reactions.

♦ On Day 8 you will receive Gemcitabine intravenously by vein (IV) over about 90 minutes, followed by docetaxel by vein over about 30 minutes.

♦ On Day 9, you will get an injection to help your white blood cells stay closer to normal and to decrease the risk of infection. Your doctor will give you either filgrastim daily for about 7 days, or pegfilgrastim, which only needs to be given on one day (Day 9 or 10). You or a caregiver may be taught to give this injection or you may come in to your doctor’s office or infusion center to receive this injection.

♦ Dexamethasone and G-CSF are standard drugs that are given to help reduce some of the side effects of your chemotherapy treatment.

♦ You will continue this treatment cycle with gemcitabine and docetaxel every 3 weeks for 4 cycles.

**Chemotherapy treatment: doxorubicin for 4 cycles**

♦ After all 4 cycles of the gemcitabine and docetaxel, you will receive Doxorubicin intravenously by vein (IV) over about 10 minutes every three weeks.

♦ You may also receive Neupogen on Days 2-8 or Neulasta on Day 2 or 3 if your doctor feels this is necessary.
After your treatments/observation are completed (FOR BOTH GROUPS A and B):

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 every 4 months for the first 3 years, then every 6 months for 2 years:

- History and physical examination which may include pelvic examination.
- CT scan of the chest, abdomen, and pelvis, or CT scan of the chest and MRI of the abdomen and pelvis.

Study Chart for **Group A** (Standard Treatment Group)

The chart below is another way to show what will happen to you during the study, if you are assigned to the Standard Treatment Group.

<table>
<thead>
<tr>
<th>Day</th>
<th>What you do</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within 3 to 4 weeks before starting study</strong></td>
<td>♦ Have history taken and complete physical exam which may include pelvic exam.</td>
</tr>
<tr>
<td></td>
<td>♦ CT scan of the chest, abdomen and pelvis or CT scan of the chest and MRI of the abdomen and pelvis to confirm there is no evidence of cancer.</td>
</tr>
<tr>
<td></td>
<td>♦ Get an Electrocardiogram.</td>
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<tr>
<td><strong>Every 3-4 weeks for the first 6 months</strong></td>
<td>♦ Receive a telephone call from a nurse or doctor to ask if you are experiencing any side effects.</td>
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<tr>
<td><strong>Approximately 4 months from start of the study</strong></td>
<td>♦ Have history taken and complete physical exam which may include pelvic exam.</td>
</tr>
<tr>
<td></td>
<td>♦ CT scan of the chest, abdomen and pelvis or CT scan of the chest and MRI of the abdomen and pelvis to check to see if the cancer has come back</td>
</tr>
<tr>
<td></td>
<td>♦ Blood tests to measure blood cell counts, blood mineral levels, and check liver and kidney function.</td>
</tr>
<tr>
<td><strong>Every 4 months for 3 years; then every 6 months for 2 years</strong></td>
<td>♦ Have history taken and complete physical exam which may include pelvic exam.</td>
</tr>
<tr>
<td></td>
<td>♦ CT scan of the chest, abdomen and pelvis or CT scan of the chest and MRI of the abdomen and pelvis to check to see if the cancer has come back</td>
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The CHART below in another way to show what will happen to you during the study, if you are assigned to the Experimental Treatment Group.

### What you do during the treatment with Gemcitabine and Docetaxel, for 4 cycles

#### Day

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Action Details</th>
</tr>
</thead>
</table>
| Within 3 to 4 weeks before starting study | ♦ Have history taken and complete physical exam which may include pelvic exam.  
♦ CT scan of the chest, abdomen and pelvis or CT scan of the chest and MRI of the abdomen and pelvis to confirm there is no evidence of cancer.  
♦ Have an Electrocardiogram.  
♦ Have an ECHO or MUGA scan if your doctor tells you to. |
| Within 14 days before starting treatment | ♦ Have routine blood tests.                                                   |
| Day 1                                   | ♦ Go to your doctor’s office or infusion center for treatment. Receive Gemcitabine chemotherapy by vein over about 90 minutes. |
| Day 8                                   | ♦ Go to your doctor’s office or infusion center for treatment. Receive Gemcitabine chemotherapy by vein over about 90 minutes, and docetaxel by vein over about 30 minutes.  
♦ Have routine blood tests. |
| Day 9 or 10                             | ♦ Receive an injection with filgrastim or pegfilgrastim to lower your risk of infection. If you receive filgrastim you will receive it daily for about 7 days (Days 9-15). If you receive pegfilgrastim you will receive it on Day 9 or 10. |
| Day 21                                  | ♦ Get routine blood tests and exams.                                          
♦ Have history taken and complete physical exam which may include a pelvic exam.  
♦ Return to your doctor’s office for your next exam and to begin the next cycle of Gemcitabine + Docetaxel. You will have a total of 4 cycles of Gemcitabine + Docetaxel. |

### What you do during treatment with Doxorubicin*, for 4 cycles

#### Day

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Action Details</th>
</tr>
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<tbody>
<tr>
<td>Day 1</td>
<td>♦ Go to your doctor’s office or infusion center for treatment. Receive Doxorubicin chemotherapy by vein over about 5-10 minutes.</td>
</tr>
<tr>
<td>Day 2 or 3</td>
<td>♦ Receive an injection with filgrastim or pegfilgrastim to lower your risk of infection, if your doctor recommends it. If you receive filgrastim you will receive it daily for about 7 days (Days 2-8). If you receive pegfilgrastim you will receive it on Day 2 or 3.</td>
</tr>
</tbody>
</table>
| Day 21      | ♦ Get routine blood tests and exams.                                          
♦ Have history taken and complete physical exam which may include a pelvic exam.  
♦ Return to your doctor’s office for your next exam and to begin the next cycle of Doxorubicin. You will have a total of 4 cycles of Doxorubicin. |
Day | What you do
---|---
Every 4 months for 3 years; then every 6 months for 2 years | ♦ Have history taken and complete physical exam which may include pelvic exam.  
♦ CT scan of the chest, abdomen and pelvis OR CT scan of the chest and MRI of the abdomen and pelvis to check to see if the cancer has come back.

* If your heart function tests showed that you have lower than normal heart function, you will NOT receive treatment with doxorubicin. You will remain on study and proceed with follow-up as detailed for all patients in Group B.

**HOW LONG WILL I BE IN THE STUDY?**

You will be asked to visit the office for follow up exams approximately every four months for the first three years and then every six months for the next two years after enrollment on this study. At the end of this five year period we would like to keep track of your medical condition for the rest of your life by calling you once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term results of the study.

**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 side effects/risks from treatment 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, or 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 don’t 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. For the patients assigned to Group B, many side effects go away soon after the treatments with the gemcitabine + docetaxel, and doxorubicin, are finished. 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. There also is a risk of death.

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

The possible side effects of the chemotherapy drugs used in this study are listed below. If you are assigned to Group B, you might experience some of these side effects.

Risks and side effects related to **Gemcitabine** include those which are:
Likely:
- Low white blood cell counts that could lead to infection
- Low red blood cell counts that could cause anemia
- Mild nausea
- Fatigue
- Hair loss
- Numbness or tingling in the hands and/or feet

Less Likely
- Flu-like symptoms such as fatigue, muscle aches, fever lasting 1-2 days after gemcitabine treatments
- Infection requiring treatment with medicines
- Low platelets that could lead to bleeding
- Nausea and vomiting
- Diarrhea or constipation
- Mouth sores may occur; you will be given treatment to make them more tolerable. Mouth sores improve over time.
- Abnormalities in the blood tests that measure liver function
- Fluid retention in the feet, legs, and weight gain
- Kidney function abnormalities, with the appearance of protein or blood in the urine
- Rash may occur, involving the body and/or legs
- Changes in taste, or a metallic taste

Rare but serious
- Confusion, hearing problems, heart failure, abnormal heart rhythms, high blood pressure, low blood pressure, blood clots in the legs or lungs, bowel obstruction, bleeding, severe infections leading to death. The relationship of these events to the administration of the chemotherapy drugs has not been proven, since all patients who have received these drugs have underlying cancer, which may cause some or all of these effects by itself.
- Rarely, severe lung damage has occurred in patients being treated with the combination of gemcitabine and docetaxel. In most cases the lung problems improve when the treatments were stopped.
- Rarely, a condition affecting the blood and kidneys called hemolytic uremic syndrome has occurred. When this occurs the kidney damage can sometimes be permanent.
Risks and side effects related to the Docetaxel include those which are:

**Likely:**
- Low white blood cell counts - this may make you more susceptible to infection
- Low platelet count - this may make you bruise more easily and bleed for longer if injured
- Low red blood cell count which may cause tiredness, shortness of breath or fatigue
- Mild to severe allergic reaction which may be life-threatening with hives, wheezing and low blood pressure
- Numbness and pain of the hands and feet that sometimes worsens with additional treatment and may not disappear after the drug is stopped. This may lead to difficulty walking, buttoning clothes, etc.
- Hair loss
- Muscle weakness and muscle loss; muscle and joint aches
- Shortness of breath
- Skin irritation (including hives and itching if allergic reactions)
- Low or high blood pressure
- Nausea and/or vomiting
- Diarrhea
- Mouth and throat sores (that can lead to difficulty swallowing and dehydration)
- Fatigue
- Excessive tearing of the eyes
- Chills; fever
- Fluid retention, in the form of weight gain, poorly tolerated swelling of the legs, arms, tissues beneath the skin, sometimes fluid collections in the chest causing shortness of breath and strain on the heart, and sometimes fluid collections in the abdomen (ascites) which can cause abdominal discomfort, distention and indigestion.
- Nail changes (e.g., discoloration, fungal infection, bleeding under the nail, etc.)

**Less likely, but serious:**
- A slowing of the heart rate (a slow pulse is not harmful; however if you should develop any other irregularities in heart rate during treatment, an ECG and other tests may be required.)
- Irregular heartbeats
- Heart attack
- Lightheadedness
- Headaches
- Kidney damage
- An increase in triglycerides (a blood lipid) levels which could increase risk of hardening of the arteries
- Liver damage
Confusion; mood changes
Skin tissue damage if some of the drug leaks from the vein while it is being given
Changes in taste
Irritation and swelling of the skin in an area previously treated with radiation therapy
Rash
Inflammation of the colon, pancreas or lungs
Blurred vision or other changes in eyesight such as sensation of flashing lights or spots
Infection and/or bleeding complications as a result of decreased blood counts

Rare, but serious:
Liver failure
Swelling of the Brain
Seizures
severe allergic reaction resulting in development of a rash, difficulty breathing, and low blood pressure
Acute leukemia

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

**Likely:**
Temporary lowering of the number of white blood cells (cells that help your body fight infection)
Temporary lowering of the number of red blood cells (may cause a feeling of tiredness, and shortness of breath)
Temporary lowering of the number of blood platelet cells (cells that help your blood clot) which could cause bleeding
Nausea, vomiting, abdominal pain or diarrhea
Loss of appetite
Temporary loss of scalp and body hair
Skin and nail discoloration
Sores in the mouth and/or throat
Urine may turn red for 1 to 2 days (due to the color of the doxorubicin)
Sensitivity to sunlight
Less Likely, but Serious:

- Heart damage
- Irregular heart beat (may occur right after the drugs are given)
- Congestive heart failure (swelling, fluid in the lungs, a decrease in the heart’s ability to pump effectively, which may lead to shortness of breath)
- Skin tissue damage if some of the drug leaks from the vein while it is being given
- Serious, potentially life threatening allergic reaction
- Damage to the liver
- Irritation and swelling of the skin in an area previously treated with radiation therapy

Rare:

- Acute leukemia

The side effects of the filgrastim (also known as Neupogen or G-CSF) include bone pain and increased levels of some blood tests. Less frequent side effects include enlarged spleen, worsening of previous skin rashes, hair loss, decreased platelets and inflammation of the blood vessels. Rarely, the spleen has ruptured and in very few cases this has resulted in death. The spleen is located in the upper left section of your abdomen. If you feel pain in your abdomen or pain in your left shoulder, contact your doctor immediately. Very rare events have occurred in patients receiving chemotherapy drugs and Neupogen that included decreased blood supply to the intestines, inflammation of the intestine, and perforation of the intestine; it is not known if Neupogen contributed to these events or if they were caused by the chemotherapy. Rarely, allergic reactions have occurred causing skin rash, hives, fluid retention, wheezing, difficulty breathing, decreased blood pressure, and increased heart rate.

The side effects of pegfilgrastim (also known as Neulasta or G-CSF) include bone pain and increased levels of some blood tests. One case of a ruptured spleen has been reported following the administration of Neulasta. The spleen is located in the upper left section of your abdomen. If you feel pain in your abdomen or pain in your left shoulder, contact your doctor immediately. Rarely, allergic reactions have occurred, causing skin rash, hives, fluid retention, wheezing, difficulty breathing, decreased blood pressure, and increased heart rate.

Reproductive risks: In order to be able to go on this study, patients are required to have had surgery to remove the uterus (hysterectomy). Women without a uterus are not able to become pregnant. Women should not breastfeed a baby while on this study.

For more information about risks and side effects, ask your study doctor.
ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
Taking part in this study may or may not make your health better. Doctors do not know whether giving chemotherapy with gemcitabine + docetaxel, followed by doxorubicin, will decrease the chance that leiomyosarcoma comes back. We do know that the information from this study will help doctors learn whether this treatment will decrease the chance that leiomyosarcoma comes back after surgery, and whether patient who get treatment with gemcitabine + docetaxel, followed by doxorubicin live longer than patients who are closely observed, or whether they do not. This information could help future patients with leiomyosarcoma.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?
Your other choices may include:
♦ Being closely observed after surgery or getting treatment without being in a study
♦ Taking part in another study
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 in USA, to be reviewed and analyzed by physicians and other Study personnel. Your records may be accessed by GOG representatives, EORTC, NCRN, the Cancer Trials Support Unit (CTSU), and by the NCI for research in USA, quality assurance, and data analysis purposes.

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](http://www.ClinicalTrials.gov). 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 to withhold that information.
WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Investigations or blood tests performed only because you participate in this clinical study will not be charged to you.

WHO IS LEGALLY RESPONSIBLE FOR THE STUDY (SPONSOR) AND HOW IS THIS STUDY BEING FUNDED?

EORTC is legally responsible (sponsor) for this study in Europe.

This clinical study is performed with financial support from EORTC and NCRN (only for UK participants) to support its conduct.

The doctor conducting the research will not be paid for including and looking after patients in the study. Neither will you be paid for your participation in the study.

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.

In compliance with applicable legislation EORTC, as sponsor, has taken out insurance to cover potential risks related to your participation in this clinical study.

WHO APPROVED THIS STUDY?

This study has been approved following national and European legislation.

Among other approvals, research protocol for this clinical study has been reviewed by an independent group of people, called an ethics committee, whose purpose is to verify that all conditions with regard to your safety and rights are respected. This study has been reviewed and given a favorable opinion by the ethics committee of ___________ (institution and city) on ___________ (date).
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].

You may wish to inform your family physician who may also answer some of your questions.

The study results of this are expected to be published not sooner than 2018.

Results of the study may be published in medical journals and public medical databases like EudraCT.

You can search on: www.clinicaltrials.gov.

You can also contact your study doctor afterwards if you want to know whether results of your study have been published and/or to have additional explanation.

[Alternatively patient organizations in your country may help you to search for results or to understand them. Provide reference]

Signature

I have been given a copy of all ______ [insert total of number of pages] 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.

________________________  __________  __________
Name of participant or legal representative  Date  Signature

________________________  __________  __________
Name of investigator or person designated by the investigator to take part in the informed consent process  Date  Signature