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CONSENT FORM

URCC 1105: Prevention of Delayed Nausea A Phase III Double-Blind Placebo-Controlled Clinical Trial.

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URCC 1105: Prevention of Delayed Nausea A Phase III Double-Blind Placebo-Controlled Clinical Trial.

Introduction

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 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.

You are being asked to take part in this study because you have been diagnosed with cancer and are scheduled to receive chemotherapy for the first time containing cisplatin, carboplatin, oxaliplatin, doxorubicin or epirubicin. While these drugs are often very effective in treating cancer, they do cause nausea in some patients. Because of this, you will receive one of two standard anti-nausea drugs: granisetron (Kytril®), or palonosetron (Aloxi®), along with dexamethasone (Decadron®), on the day of your treatment (Day 1). These two medications are considered equal in nausea control and are the best available medicines to combat nausea occurring on the day of your treatment. You may also receive an additional anti-nausea drug, aprepitant (Emend®), on the day of treatment. This drug may improve the control of nausea, although that is not certain. We also want to find the best medicine for reducing or eliminating nausea that might occur one or more days after your chemotherapy (delayed nausea).

Why is this study being done?

Despite the widespread use of a variety of anti-nausea medications, delayed nausea can still occur following chemotherapy treatment with cisplatin, carboplatin, oxaliplatin, doxorubicin and epirubicin. The purpose of this study is to compare the effectiveness of four commonly prescribed drug combinations for the control of delayed nausea in people with cancer receiving chemotherapy containing cisplatin, carboplatin, oxaliplatin, doxorubicin or epirubicin. We also want to look at your quality of life while you are on this study.

How many people will take part in the study?

Approximately eight hundred and ninety patients will take part in this study nationally.

What will happen if I take part in this research study?

If you agree to participate in this study, you will be randomized into one of the four 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 the researcher can choose the group you will be in. You will have an equal chance of being placed in any of the four groups.

All participants will receive current standard anti-nausea medications (described in the Introduction) on the day of treatment. Medications on the day of treatment will be given intravenously (through a vein) just before your intravenous chemotherapy is given. The four groups differ in what medications participants will take on the two days following treatment.

Medications on the two days after treatment will be in capsule form, and all participants will take four capsules on each of those two days, two in the morning, one at midday and one in the evening. Some of the capsules may contain a placebo (an inactive substance). Your doctor is allowed to give you rescue medications as necessary if your nausea is not controlled by these drugs. You will take the medications on Days 2 and 3 whether or not you have any nausea.

Arm	Day 1 Medications (Day of Treatment)	Day 2 & Day 3 Medications		
		morning	midday	evening
Arm 1	Palonosetron Dexamethasone Placebo	Compazine 10 mg Placebo	Compazine 10 mg	Compazine 10 mg
Arm 2	Granisetron Dexamethasone Placebo	Compazine 10 mg Placebo	Compazine 10 mg	Compazine 10 mg
Arm 3	Aprepitant Palonosetron Dexamethasone	Aprepitant 80 mg Dexamethasone 8 mg	Placebo	Placebo
Arm 4	Palonosetron Dexamethasone Placebo	Compazine ¹ Dexamethasone 8 mg	Compazine 10 mg	Compazine 10 mg

This is a double-blinded study, which means that neither you nor your doctor will know which of these drug combinations you will receive. These medications will be provided as part of the study.

Before your treatment begins, you will be asked to complete paper and pencil questionnaires that ask about symptoms you may be having, the amount of exercise you typically engage in and your quality of life. Filling out the questionnaires will take approximately 20 minutes. After your treatment, you will also be asked to complete a 4-day home record of any additional anti-nausea medication you took and your degree of nausea and vomiting, as well as questionnaires that ask about symptoms, exercise and quality of life. You will be given a stamped addressed envelope in which to mail the completed forms back.

We will call you on day 4 of the study to remind you to return the questionnaires. We will also ask you to bring your used pill pack back to the clinic at your next chemotherapy treatment.

How long will I be in the study?

You will be in the study for four days.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the researcher and/or your regular doctor if you are thinking about stopping or decide to stop. That person will tell you how to stop safely.

The researchers may stop you from taking part in this study at any time if they believe it is in your best interest, 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. Many side effects go away soon after you stop taking the medication. In some cases, side effects can be serious, long lasting, or may never go away.

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

The medications given in this study are standard medications (the most effective, and therefore the most commonly used medications) for control of chemotherapy-induced nausea and vomiting.

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

Likely:

- drowsiness

Less Likely:

- dizziness
- blurred vision

Rare but Serious

- Involuntary movements of the body can develop, usually in patients taking Compazine in higher doses and for longer times than prescribed in this study. Caution should be used when driving or using machinery while taking this drug. You should avoid drinking alcohol while taking this drug.

Risks and side effects related to the **granisetron (Kytril®)** or **palonosetron (Aloxi®)**:

Less Likely:

- headaches
- constipation
- diarrhea

Risks and side effects related to the **Aprepitant, (Emend®)**:

Less Likely:

- fatigue
- dizziness
- diarrhea
- stomach discomfort
- hiccups
- nausea
- anorexia (loss of appetite)
- abdominal pain

Risks and side effects related to the **dexamethasone (Decadron):**

Less Likely:

- appetite change
- upset stomach
- edema (swelling of legs)
- difficulty sleeping
- nausea
- vomiting
- headache
- dizziness
- mood swings

Reproductive risks: You should not become pregnant while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Sexually active participants who are relying on oral contraceptives to prevent pregnancy should use a barrier method of contraceptive while participating in this research study. Check with your doctor about what kind of birth control methods to use and how long to use them. For more information about risks and side effects, ask the researcher.

Are there benefits to taking part in the study?

It is not possible to predict whether you will receive any personal benefit from participating in this research study. We hope the information learned from this study will benefit other patients with chemotherapy-related nausea in the future.

What other choices do I have if I do not take part in this study?

Instead of being in this study, you can receive whatever anti-nausea medications your doctor prescribes, including the medications used in this study. You may discuss other treatment options with your doctor.

Will my medical information be kept private?

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people, as explained below, may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) require us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use your research record, related information from your medical records, results of laboratory tests, questionnaires and diaries you complete, and both clinical and research observations made while you take part in the research.

We will use your health information to conduct the study, to monitor your health status, to measure effects of drugs/devices/procedures, to determine research results and possibly to develop new tests, procedures, and commercial products.. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. You may see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of you Consent Form or HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: the sponsor (National Cancer Institute); the Food and Drug Administration (FDA); the Department of Health and Human Services; MGI Pharma; the University of Rochester; and affiliated research sites of the University of Rochester Cancer Center Community Clinical Oncology Program.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others. For example, by Federal law, we must send study information to the FDA for drug and device studies it regulates. Information that may need to be reported to FDA cannot be removed from your research records.

As stated in the section “What are my rights if I take part in this study?” below, you can also refuse to sign this consent and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

What are the costs of taking part in this study?

Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems. All study medications will be provided free of charge with one exception. If your doctor prescribes the additional drug Reglan to help with nausea in the days after your treatment, this drug will not be provided free of charge.

You will not be paid for taking part in this 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?

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

What are my rights if I take part in this study?

Participation 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. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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

For questions about your rights while taking part in this study please contact your study doctor at the number on the cover sheet or the MultiCare Health System Institutional Review Board at 253-403-3844.

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) or TTY: 1-800-332-8615

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/>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Signatures:

I have read the contents of this consent form, asked questions, and received answers concerning areas I did not understand. I give my consent to participate in this study by signing this form. I will receive a copy of this form for my records.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

**Authorization (Permission) to Use or Disclose (Release)
Identifiable Health Information for Research**

Participant's Name: _____

Birth Date: _____

1. What is the purpose of this form?

The University of Rochester (URCC) is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a URCC research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

You may request a blank copy of the URCC data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my personal health information?

The Northwest Community Clinical Oncology Program (Northwest CCOP) will collect your health information and share it with the URCC Biostatistical Center and the URCC Operations Center if you enter a cooperative group research study. The URCC centers will use your information in their cancer research study.

You are being asked to take part in a study known as **URCC 1105: Prevention of Delayed Nausea A Phase III Double-Blind Placebo-Controlled Clinical Trial.**

4. *Who will be able to use my personal health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. The Northwest CCOP may also permit these groups to come in to review your original records that are kept by the Northwest CCOP so that they can monitor their research study.

- the URCC Operations Center;
- the URCC Biostatistical Center;
- National Cancer Institute (NCI)
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- other people or organizations assisting with URCC research efforts
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the five bullets above.

5. *How will information about me be kept private?*

The URCC will keep all patient information private to the extent possible, even though the URCC is not required to follow the federal privacy laws. Only researchers working with the URCC will have access to your information. The URCC will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

6. *What happens if I do not sign this permission form?*

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. *What happens if I want to withdraw my permission?*

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. She will make sure your written request to withdraw your permission is processed correctly.

Karyn Hart, RHIT, CCRP
Program Coordinator
Northwest CCOP
315 Martin Luther King Jr., Way M/S 315-L2-CCO
Tacoma, WA 98405
(253) 403-1461

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by Northwest CCOP. You do not have the right to review and/or copy records kept by the URCC or other researchers associated with the research study.

Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Patient or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Permission: _____ Date: _____

Printed Name of Person Obtaining Permission: _____