SWOG S1415CD
Revision #6
Version Date 6/13/2018

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

Study Title for Study Participants:

"TrACER": Trial Assessing CSF prescribing Effectiveness and Risk

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

S1415CD, "A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia –Trial Assessing CSF Prescribing Effectiveness and Risk ("TrACER")"

Why is this study being done?

Some drugs used to treat cancer raise a patient's risk of febrile neutropenia. Febrile neutropenia is a condition that involves a fever and a low number of neutrophils (a type of white blood cell) in the blood. Having a low number of neutrophils puts a patient at risk of infection. Colony-stimulating factors (CSFs) are medications sometimes given to patients getting cancer treatment to prevent or treat febrile neutropenia. CSFs are given as an injection under the skin or into a vein.

Current guidelines say that doctors should give CSF during cancer treatment based on how likely it is that the drugs will raise the risk of febrile neutropenia. Research shows that many doctors do not follow these guidelines. This may be harming patients. Underuse of CSFs can raise a patient's risk for febrile neutropenia. Overuse or unneeded use of CSFs can lead to side effects, like bone and muscle pain, but give no benefit and can be costly to the patient.

In some clinics there is an automated system that helps doctors decide when to use CSFs. The system prescribes CSFs when there is a high risk that the drugs will cause febrile neutropenia. It does not prescribe CSFs when there is a low risk that the drugs will cause febrile neutropenia. The research study team wants to find out if this type of system can help doctors use CSF when it is needed and not use it when it is not needed. The study team also wants to learn about the benefits and risks of using CSF with cancer treatment drugs that have a moderate (not high and not low) risk of febrile neutropenia.

Approval Date 9/13/2018 to 6/13/2019

Assurance#: FWA00003582

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You are being asked to take part in this study because you will be receiving cancer treatment at a clinic that has chosen to take part in this study. Clinics that choose to take part in this study are assigned to one of the following four groups.

Clinic Group #1: Clinics that already have an automated system that helps doctors decide when to use CSFs will be assigned to Group #1. These systems prescribe CSFs when there is a high risk that the cancer treatment drugs will cause febrile neutropenia. They do not prescribe CSFs when there is a low risk that the drugs will cause febrile neutropenia. The study will not ask these clinics to change what they usually do. These clinics will use their existing system to decide when to use CSFs. For patients at these clinics, care will not be different from care that they would receive outside the study. There are eight clinics participating in the study in Group #1.

Clinics that do not have an automated system will be assigned to Clinic Group #2, #3, or #4. A computer will assign each clinic to a group by chance. This is called randomization. Assignment is done by chance because no one knows if one study group is better or worse than the others.

Clinic Group #2: At clinics assigned to Group #2, no automated system is installed. The study will not ask these clinics to change what they usually do. For patients at these clinics, care will not be different from care that they would receive outside the study. There are eight clinics participating in the study in Group #2.

Clinic Group #3: Clinics assigned to Group #3 do not have an automated system, but will have an automated system installed as part of this study. The system will suggest that CSFs be used for cancer treatment drugs that have a high risk or moderate risk of febrile neutropenia. The difference between Group #3 and Group #4 is that for clinics in Group #3, the system will suggest that CSF be used for regimens that have a moderate risk of febrile neutropenia. The system will suggest that CSFs not be used for drugs that have a low risk of febrile neutropenia. If the doctor does not agree with the suggestion from the system, he or she does not need to follow it. For patients at these clinics, cancer treatment will not be different from the treatment that they would receive outside the study. However, the study may affect whether the patient receives CSFs. There are twelve clinics participating in the study in Group #3.

Clinic Group #4: Clinics assigned to Group #4 do not have automated system, but will have an automated system installed as part of this study. The system will suggest that CSFs be used for cancer treatment drugs that have a high risk of febrile neutropenia. The system will suggest that CSFs not be used for drugs that have a low or moderate risk of febrile neutropenia. The difference between Group #3 and Group #4 is that for clinics in Group #4, the system will suggest that CSF *not* be used for drugs that have a moderate

Approval Date 9/13/2018 to 6/13/2019

Assurance#: FWA00003582

risk of febrile neutropenia. If the doctor does not agree with the suggestion from the system, he or she does not need to follow it. For patients at these clinics, cancer treatment will not be different from the treatment they would have received outside the study. However, the study may affect whether the patient receives CSFs. There are twelve clinics participating in the study in Group #4.

Your clinic has been assigned to Group #___.

There will be about 3,600 people taking part in this study (about 90 people in this clinic).

What is the usual approach to use of medical information for research?

If you agree to be in the study, the study team will review your medical records and your responses to questionnaires to answer research questions.

Hospitals or doctor's offices usually use a "Release of Medical Information" form to get medical information from patients. For this study, the researchers are using a consent form that describes what type of information they want from your medical records. The consent form asks your permission to use this information from your medical records along with your answers to the questionnaires for research.

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

Your decision to participate (or not to participate) in this research study will NOT affect your cancer treatment. If you decide not to take part in this research study, you have other choices. For example:

- You can get treatment for your cancer without being on a study
- You may choose to take part in a different study, if one is available

How long will I be in this study?

You will be in the study for 12 months.

What is involved?

If you agree to take part in the study, information from your medical records will be obtained at the following times:

Approval Date 9/13/2018 to 6/13/2019

Assurance#: FWA00003582

- At the time you join the study (baseline)
- After the first cycle of treatment
- 1 month after you join the study
- 6 months after you join the study
- 12 months after you join the study

The researchers will obtain the following information from your medical record:

- Basic information about you (e.g., gender, height, weight)
- Type of cancer
- Your medical history, current medical issues, health status
- Name of cancer treatment drugs and amount (planned and received)
- Name of CSFs and amount received
- Names of other drugs received during treatment
- Occurrence of febrile neutropenia (including related hospital and emergency room visits)
- Side effects
- Blood test results

You will also be asked to answer questionnaires at the following times:

- At the time you join the study (baseline)
- After the first cycle of treatment
- 6 months after you join the study

The researchers will obtain the following information, directly from you, through the questionnaires:

- Information about you (education level, income level)
- Physical problems not related to cancer
- Information about out of pocket expenses for your treatment
- What you know about CSF drugs and febrile neutropenia
- Information about how and where you received CSFs and antibiotics
- Information about your physical, emotional, and social well-being and how well you are functioning

You will be given up to three questionnaires at each time point: three at baseline, two at the end of your first cycle of treatment and one at 6 months. It may take between 15-20 minutes to answer the questionnaires (each time you answer them). The researchers would like for you to fill out the questionnaires during the clinic visit. You may fill out the questionnaires at home, or

Approval Date 9/13/2018 to 6/13/2019

Assurance#: FWA00003582

over the phone. If you fill out the questionnaires at home, you can either mail them back to the research staff using a pre-addressed stamped envelope that will be provided, or you can bring them with you the next time you come into clinic for an appointment. The research staff will work with you to find the easiest option for you.

What extra tests and procedures will I have if I take part in this study?

No extra testing or procedures are needed for participation in this study.

What are the possible risks of taking part in this study?

If you choose to take part in this study, there is a risk that you may feel uncomfortable being asked about your functional, physical, emotional, and social well-being.

The study team has policies in place to protect your personal information and they will do their best to make sure that the personal information used for this study will be kept private. However, they cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will **not** be used.

To help make sure your information is private, your doctor or nurse will go to a secure data submission portal sponsored by the National Cancer Institute (NCI) to send the researchers your information. The research study team can then go to the same secure portal and get your information to include it with the information from all of the other patients taking part in the study.

What are the possible benefits of taking part in this study?

The information you provide will help the researchers to better understand how doctors and clinics are prescribing CSFs and if the way they are being prescribed is effective in reducing febrile neutropenia.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

Approval Date 9/13/2018 to 6/13/2019

Assurance#: FWA00003582

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the NCI Community Oncology Research Program – Kansas City Institutional Review Board at 913-948-5588.

What are the costs of taking part in this study?

There are no costs for participating in the study. The research study team will arrange their research with your other medical appointments so that you do not need to make separate trips to the clinic for this study. The research staff will provide a stamped envelope if you choose to return questionnaires by mail.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

What happens if I am injured or hurt because I took part in this study?

There will be little risk of being injured on this study since the study team is only collecting information from medical records and questionnaires.

Who will see my medical information?

Your privacy is very important to the researchers and they will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, SWOG.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- National Cancer Institute
- Hutchinson Institute for Cancer Outcomes Research

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

Future Contact

Sometimes researchers working with SWOG may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, researchers would need to contact participants in a particular study. You can agree or not agree to future contact by circling "yes or no"

Approval Date 9/13/2018 to 6/13/2019

Assurance#: FWA00003582

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

YES **NO**

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.

My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in this study.

Participant _____

Participant's signature_____

Date of signature_____

Person obtaining consent _____

Signature of researcher obtaining consent _____

Date of signature _____

Approval Date 9/13/2018 to 6/13/2019

Assurance#: FWA00003582