Informed Consent Form

Winship4173-17: Effects on QOL when Zinc is replaced in Patients with Upper GI Cancer on Chemotherapy

NCT Number: NCT03819088

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EMORY | WINSHIP CANCER INSTITUTE

A Cancer Center Designated by the National Cancer Institute

Emory University and Saint Joseph's Hospital
Consent and Authorization to be a Research Subject

Title: Effects on QOL when Zinc is replaced in patients with Upper GI Cancers while on Chemotherapy

Principal Investigator: Aaron Jones, NP

Study-Supporter:

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

Study Overview

The purpose of this study is to assess the effects on QOL (quality of Life) when replacing zinc in upper GI cancer patients while they are receiving chemotherapy.

Approximately 100 people will take part in this study at an Emory cancer center. They will be divided evenly between the two study arms.

What are the study arms?

This study has two arms. There will be a total of 100 subjects on this trial, 50 on each arm as follows:

- Arm A, the first 50 subjects, will take 220 mg of zinc orally three times a day for months 1 and 2 only of the first 4 months of therapy
- Arm B, the second 50 subjects, will take 220 mg of zinc orally three times a day for months 3 and 4 only of the first 4 months of therapy

Procedures

Prior to starting chemotherapy (Within 2 weeks)

- One teaspoon of blood for zinc level-blood will be taken with a regular blood draw- no extra sticks. The blood draw is for clinical purposes and the study involves adding a zinc level to standard lab test
- Quality of life questionnaire- time 5 to 10 minutes
- Arm A will receive and take zinc 220 mg three times a day

Two months after starting chemotherapy (+/- 2weeks)

- One teaspoon of blood for zinc level-blood will be taken with a regular blood draw- no extra sticks. The blood draw is for clinical purposes and the study involves adding a zinc level to standard lab test
- Quality of life questionnaire- time 5 to 10 minutes
- Arm A will stop taking zinc
- Arm B will receive and take zinc 220 mg three times a day

Four months after starting chemotherapy (+/- 2weeks)

- One teaspoon of blood for zinc level-blood will be taken with a regular blood draw- no extra sticks. The blood draw is for clinical purposes and the study involves adding a zinc level to standard lab test
- Quality of life questionnaire - time 5 to 10 minutes
- Arm B will stop taking zinc

Zinc Levels will be monitored by a blood test. If zinc level is 1.5 times greater that ULN (upper limits of normal) zinc will be stopped.

Risks and Discomforts

Risk of Blood Drawing: Putting a needle in your vein to draw blood may hurt when the needle is put in. There is a risk of continued pain, bruising, dizziness, fainting or infection, which although rare, can occur. **Note there is no added needle sticks**, the blood test is added to standard of care blood draws

- The time it will take to complete the Quality of life questionnaire
- There is possible confidentiality risk in research, but we will do everything we can to prevent this from happening
- Some people may find the Quality of Life questionnaire distressing since they have to record how they are feeling and they may not be feeling well
- Zinc package insert suggest a potential for nausea
- If you are a female with the potential to become pregnant, an adequate birth control method will need to be used while taking zinc on this study.

New Information
It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits
This study is not designed to benefit you directly. Your condition may improve while you are in this study but it may not, and it may even get worse. The study results may be used to help others in the future.

Payment for Participation
You will not be offered payment for being in this study.

Other Treatment outside this Study
Your alternative is not to take part in it.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information
De-identified data from this study, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record
If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory and Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Saint Joseph's Hospital medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study

information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: Zinc level.

Tests and procedures done at non-Emory and Saint Joseph's Hospital places may not become part of your Emory and Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Should you choose to stop being in the study, you will need to tell your study doctor in writing. Data collected up until you tell us not to may still be used for research purposes.

There is a risk of breach of confidentiality that cannot be totally eliminated. To minimize that risk, electronic data will be stored in a secure network that is password protected and hardcopy data will be secured in a locked office.

In Case of Injury

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital would help you to get medical treatment. Emory, Saint Joseph's Hospital and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory, Saint Joseph's Hospital or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Aaron Jones, NP or Tiffany Brown, RN at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study in which you may choose to participate.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.

- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Winship Cancer Institute is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices and Saint Joseph's Hospital that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight

offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Aaron Jones, NP
Winship Cancer Institute, Emory University
1365-C Clifton Road, NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Withdrawal from the Study
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to go off the study. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Contact Information

Contact Aaron Jones, NP, or Tiffany Brown, RN at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ ____:____ am / pm
Signature of Subject (18 or older and able to consent) **Date** **Time (please circle)**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ ____:____ am / pm
Signature of Person Conducting Informed Consent Discussion **Date** **Time (please circle)**