Randomized Control Trial: Intravenous Iron Versus Oral Iron for the Treatment of Iron Deficiency Anemia in Pregnancy

Date: 11/21/2023

Arrowhead Regional Medical Center
Informed Consent Form for Participation in a Research Project

Study Title: Early Intravenous Versus Oral Iron for Ferritin-Defined Iron Deficiency in Pregnancy: A Prospective Comparative Study
Principal Investigator: *Guillermo Valenzuela*

Introduction:
You are being asked to join a research study. You are being asked to take part in this study because *you are diagnosed with iron deficiency anemia.* You do not have to participate in this research study. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There is no penalty if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at Arrowhead Regional Medical Center.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about this research. You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

Purpose:
You are invited to be part of a research study about *iron deficiency anemia*

The purpose of the study is to *evaluate the efficacy of IV iron in the treatment of anemia* You are invited to be in this study because *you were diagnosed with anemia*

The persons responsible for the research project are *Guillermo Valenzuela, Shirely Wong, Kristina Roloff, Robert Stowe, Tina Bui, Mary Tsaturian, Phoebe Jen, Lily Zhu.* Your doctor is interested in your health as well as conducting this research project. If you feel that your doctor can not represent your best interest, you can ask for another doctor to take care of you.

Description of your Involvement:
If you are eligible and decide to participate in this study, your participation will last approximately *up until the treatment duration and until the scheduled surgery/delivery. If you are eligible for this study, you will be assigned to one of two treatment groups based on a predetermined alternating allocation sequence. Your treatment group will be determined before you are asked to provide consent to participate in the study. You will have the opportunity to review the study information, ask questions, and decide whether or not to participate after learning which treatment group you have been assigned to.If assigned*

Subject Initials: _____
Date: _____

to the oral iron group, you will take ferrous sulfate 325 mg by mouth every other day. If assigned to the intravenous (IV) iron group, you will receive an infusion of iron sucrose 200 mg intravenously over approximately 15 minutes. Multiple IV iron infusions may be necessary depending on the degree of iron deficiency. You will continue to receive routine prenatal care and will be followed in the clinic as usual. We do not anticipate that these medications will add any further reactions. Furthermore, the management of your care will not change. We/I would also record your demographics, medical history including pregnancy history, physical exam, vital signs, height and weight for the purpose of this study. Your name and identity will be protected.

Risks and Discomforts of Participation:
There may be some risk or discomfort from your participation in this research. This study *minimal risk. There are not anticipated health risks for you or your fetus from your participation in this research.* Participating in this study will involve the following risks: *There may be some side effects from the medications, however, this should not harm the fetus or the participant. The patient's data will be stored on a password protected document to decrease the risk of breach of confidentiality.*

All records and research materials that identify you will be held confidential. Any published document resulting from this study will not disclose your identity without your permission. Information identifying you will only be available to the study personnel. *All data will be kept in a password protected folder within the ARMC network and will only be made available to study investigators. The database will be controlled, and password protected.* Your rights regarding permission to use your health information are described on the attached "Authorization for Use of Protected Health Information" form.

There may be other risks of the study that are not yet known.

Benefits:
You may or may not directly benefit from this study. Although you may not directly benefit from being in this study, others may benefit because *of what we learn about iron deficiency anemia*

Subject Rights:
You do not give up any legal rights to privacy, confidentiality, or safety by participating in this study. Participating in this study is completely voluntary. Not participating in the study will not be held against you and will not affect your access to care or treatment unrelated to this research. Even if you decide to participate now, you may change your mind and stop at any time without affecting your medical care. Your study doctor or primary care doctor can discuss alternatives with you which may include, *oral iron or expectant management of anemia.* If you decide to withdraw before this study is completed, *your data will not be used.* You will be given a copy of the California Experimental Subject's Bill of Rights and a copy of this Informed Consent to keep.

Potential Costs:
You and/or your health insurance must pay for those services, supplies, procedures, and care required for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your

Subject Initials: _____
Date: _____

insurance. If you participate in this study, there may be additional costs to you, such as travel for study visits.

Potential Compensation:
For your participation in this research project, *you will not benefit from this study. You will not be paid. You will not receive any results either. The only people who will receive the results are the investigators doing the study, and they will not release the results to you or your other physician. Any new information developed during the course of this research that may relate to your willingness to be a participant will be given to you. If there is good information that comes from the study, we may decide to share the information with other physicians through publication of the data. No patient will be reported individually, but composite of all patients will be used. In this manner, there is no manner that you are identified.*

Injured during Study:
If you feel you have been injured by taking part in this study, consult with a physician or call 911 if the situation is a medical emergency. No funds have been set aside nor any plans made to compensate you for time lost for work, disability, pain or other discomforts resulting from your participation in this research.

Storage and Future Use of Data:
Your privacy will be protected and your research records will be confidential. Your data/specimens (*will be de-identified and used for research. All data sets will be stored in a password protected folder within the ARMC network and will only be made available to study investigators. The database is monitored, and password protected. The data sets will be kept confidential and available until the study is published and then data will be erased.* It is possible that other people may need to see the information you give us as part of the study, such as organizations responsible for making sure the research is done safely and properly like the Arrowhead Regional Medical Center, government offices or the study sponsor*, full sponsor name(s), if any*.

Contact Information for the Study Team:

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact *Guillermo Valenzuela.*

Contact Information for Questions about Your Rights as a Research Participant:
If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), the IRB Coordinator is an impartial third party who is not associated with the research. You may address complaints or questions about this protocol to this person, who may be contacted at (909) 580-6336.

Subject Initials: _____
Date: _____

Participant's Statement of Consent:

- I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

_____

Printed Name of Participant

_____ _____

Signature of Participant **Date**

Subject is unable to consent/sign because _____.

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Legally Authorized Representative **Date**

Investigator's Statement

I have discussed the research project with the participant; have explained all of the information contained in the Informed Consent to the participant including any adverse reactions; the participant was encouraged to ask questions; and that all questions were answered.

_____

Printed Name of Investigator

_____ _____

Signature of Investigator **Date**

Subject Initials: _____

Date: _____