Oral Iron Versus Oral Iron Plus a Web-based Behavioral Intervention in Young Children (IRONCHILD)

Informed Consent Form

BCM IRB# H-45869

Clinicaltrials.gov NCT 04371536

Approved June 17, 2021

CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
RESEARCH STUDY

H-45869 - A SINGLE-CENTER, OPEN-LABEL, RANDOMIZED FEASIBILITY TRIAL OF STANDARD ORAL IRON THERAPY VERSUS ORAL IRON PLUS A WEB-BASED BEHAVIORAL INTERVENTION IN YOUNG CHILDREN WITH NUTRITIONAL IRON DEFICIENCY ANEMIA

Concise and Focused Presentation

When reading this form, please note that the words, "you" and "your" refers to the person in the study rather than to parent or guardian, or legal representative who might sign this form on behalf of the person in the study.

You are invited to take part in this study because you have been diagnosed with iron deficiency anemia. Your participation is voluntary. You may also choose not to be part of the study. If you do not participate in this study, you will be prescribed iron medication based on a discussion with your hematology provider.

The purpose of this study is to see which method of care will best help young children with nutritional iron deficiency anemia (IDA).

If you decide to participate and qualify for the study, you will receive one of these two methods of care:
1. Liquid iron medicine (by mouth)
2. Liquid iron medicine (by mouth) and access to a website to teach you more about iron deficiency anemia and iron medicine

There are potential risks associated with participating in this study, some of which include nausea and abdominal pain.

A benefit to participating in this study is that you may receive successful treatment to your iron deficiency to improve your overall well-being; however, there is a possibility you may not benefit from this study at all. You may withdraw from the study if you decide you no longer wish to participate.

Please see below for more details on the research study.

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Iron deficiency anemia (IDA) affects nearly half a million young children in the United States. Most children take liquid iron medicine by mouth for at least 3 months. However, some children take longer to get better with this medicine. This study is trying to compare different ways of giving iron medicine to young children.

For young children in the US, the main cause of IDA is nutritional, or not having enough iron in the foods they eat. This often happens when kids drink too much cow milk and/or not eating enough foods that have a lot of iron. Iron deficiency is most common in children ages 1 to 4 years of age, during a time that is important for brain development. More severe and long-lasting IDA is associated with worse brain development outcomes. That is why these researchers want to understand the fastest way for kids with IDA to get better.

Standard treatment is oral iron medicine for 3 to 6 months. Many children do not take their iron medicine the full amount of time needed because of side effects like abdominal discomfort, nausea, constipation, and bad taste. Different factors can contribute to patients not completing their IDA therapy. Many families do not understand how important it is to treat IDA or do not have the motivation to continue the medication.

This study will offer different methods for treating IDA, including a different method to taking the oral iron therapy.

This new method gives oral iron by increasing a family's understanding and motivation. Another research study that interviewed families of young children with IDA found ways that helped the patients to continue their therapy. Using that information, a website called IRONCHILD was created to help motivate other parents to get their children to continue the oral iron medicine.

Research studies that compare these different IDA treatment methods in young children are needed and could have benefits to short-term clinical and long-term brain development. However, we do not know whether families of young children with IDA will be willing to participate in this type of study that has different treatment methods (oral iron therapy and oral iron therapy with a web-based adherence intervention).

Your decision to participate in this study is entirely voluntary and no one can make you join. If you choose not to consent, there is no penalty or change to your medical care. You can decide to participate now, but you can change your mind later and stop participating in the study without any loss of benefits or medical care to which you are entitled. Please take as much time as you need to ask questions with the doctor who will be treating you and his/her staff, with family and friends, or with your personal physician or other healthcare professionals. Your doctor will fully answer any questions you have before you make a decision.

Up to 20 patients will take part in this study.

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.

Purpose

The goal of this clinical research study is to learn which of the two methods of care will be the best way for children with iron deficiency anemia to receive therapy.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and TCH: Texas Children's Hospital.

If you appear to qualify for the study and you sign and date this consent form, the doctor will confirm that you are eligible for the study. You will complete the following procedures:

- Medical history including prior hospitalizations, lab results, medications, diet, social and family history
- Comprehensive Physical Examination which includes measurement of your vital signs, examination of your head, eyes, ears, nose, mouth, heart, lungs, abdomen, and skin.

- Blood samples: You will not have any extra blood draws (pokes) for this study, as we will draw you blood during your routine blood draws. We will ask to take extra blood (less than half a teaspoon, or 0.5-1.0 mL) for research tests. Other blood draws that you have while on study will be for your routine care and not for research purposes..

You will be on the study for 12 weeks. You will receive dietary counseling on the amount of cow milk you may have and information sheets on iron-rich foods.

There are 2 different treatments in this study. If you enroll, you cannot choose which treatment you receive. Instead, you will be randomly assigned to one of the two treatments. That means there is a 50-50 chance you will receive liquid iron medicine by itself or you will receive liquid iron medicine with access to the website.

Depending on which method of care you are assigned to, you will complete the following procedures below.

ORAL IRON THERAPY ONLY GROUP:
You will receive liquid iron medicine by mouth once per day for 12 weeks. You will receive this medication during your first visit.
During the Week 4 visit you will compete the following procedures:
- Blood Samples: You will not have any extra blood draws (pokes) for this study, as we will draw your blood during your routine blood draws. We will ask to take about a teaspoon (5 ml) of extra blood for research tests, including tests to check on the iron levels in your body. Other blood draws that you have while on study will be for your routine care and not for research purposes.
- Focused Physical Exam which includes measurement of your vital signs, examination of your eyes, mouth, heart, lungs, abdomen, and skin.
- You will be asked of any side effects that you may be having.

During the Week 8 Visit, you will return to the clinic only to pick up your oral iron medicine.

During the Week 12 visit, you will complete the following procedures:
- Medical history including prior hospitalizations, lab results, medications, diet, social and family history
- Blood Samples: You will not have any extra blood draws (pokes) for this study, as we will draw your blood during your routine blood draws. We will ask to take about a teaspoon (5 mL) of extra blood for research tests, including tests to check on the iron levels in your body.
- Focused Physical Exam which includes measurement of your vital signs, examination of your abdomen, and skin.
- You will be asked of any side effects that you may be having.

ORAL IRON THERAPY and IRONCHILD WEBSITE GROUP:
You will receive liquid iron medicine by mouth once per day for 12 weeks. You will receive this medication during your first visit.

You will also be given access to a website called IRONCHILD. You will be shown the website, including videos, at each in-clinic visit (Baseline, Week 4, and Week 12). This website was created for you and your parent/guardian to help you learn more about the importance of taking your oral iron therapy.

The study team will show you how to use the website. You will be given a unique log-in and password with instructions on how to access the site between visits. There are 3 sessions (one per clinic visit). One session will be completed per visit, and each session should be about 15 minutes or less. You will also be able to access this website from home.

During the Week 4 visit you will compete the following procedures:
- Blood Samples: You will not have any extra blood draws (pokes) for this study, as we will draw your blood during your routine blood draws. We will ask to take about a teaspoon (5 ml) of extra blood for research tests, including tests to check on the iron levels in your body. Other blood draws that you have while on study will be for your routine care and not for research purposes.
- Focused Physical Exam which includes measurement of your vital signs, examination of your eyes, mouth, heart, lungs, abdomen, and skin.
- You will be asked of any side effects that you may be having.

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- Medical history including prior hospitalizations, lab results, medications, diet, social and family history
- Blood Samples: You will not have any extra blood draws (pokes) for this study, as we will draw your blood during your routine blood draws. We will ask to take about a teaspoon (5 mL) of extra blood for research tests, including tests to check on the iron levels in your body.
- Focused Physical Exam which includes measurement of your vital signs, examination of your abdomen, and skin.
- You will be asked of any side effects that you may be having.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Sharing and Future Research Studies with Identifiable Biospecimens

Your identifiable biospecimens collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Research Related Health Information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and TCH: Texas Children's Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Identifiable biospecimens
- Other: Medical Record Number, Phone number, Address, Email

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of

Medicine, TCH: Texas Children's Hospital, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI) and their representatives, and NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives.

The data coordinating center will have access to the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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.

The Certificate of Confidentiality will not be used to prevent disclosure of child abuse, neglect, or harm to self or others to state or local authorities.

Baylor College of Medicine and TCH: Texas Children's Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and TCH: Texas Children's Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine and TCH: Texas Children's Hospital maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine and TCH: Texas Children's Hospital to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine and TCH: Texas Children's Hospital.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research

project, the Institutional Review Board, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI) and their representatives, NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, data coordinating center, Data and Safety Monitoring Board, and TCH: Texas Children's Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Jacquelyn Powers, MD Texas Children's Hospital-Clinical Care Center; 6701 Fannin Street, Suite 1580; Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

When receiving Oral Iron Therapy, you may be at risk for the following side effects:

Common Side Effects:
- Unpleasant taste
- Temporary staining of teeth
- Constipation
- Dark stools
- Nausea

Less Common Side Effects:
- Vomiting
- Abdominal pain
- Diarrhea

There are also risks of accidental ingestion/overdose. You may be at risk for the following side effects:
- Diarrhea
- Acid in the blood and/or tissue
- Shock
- Death

Loss of Confidentiality: There is a risk of loss of confidentiality. The study staff will make every attempt to minimize this risk. A code number will be assigned to your information collected as part of this study. In all study records, you will be identified only by number and initials, not by name. Other persons who may review your health information may not be required by law to protect it and there is a risk that they may share your information with others without your permission.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: You may receive successful treatment to your iron deficiency to improve your overall well-being. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: You may choose to not participate in this study. If you do not participate in this study, you will be prescribed iron medication based on a discussion with your hematology provider. You may receive either oral (liquid) iron medication or IV iron medicine.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

There will be no charge to you or your insurance company for the liquid iron medicine.

All research labs will be covered by the research study.

Most assessments and procedures in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these assessments
and procedures will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may
be responsible for, contact your insurance company.

You may receive up to $100 for being in the study: $50 for the completion of the Week 4 visit and $50 for the completion for the Week 12 visit. You will be paid the total amount at the completion of the study. No additional money or gifts will be provided as part of your participation.

A ClinCard will be used for reimbursement, unless it is not available, in which case, cash or check will be used. Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or Legally Authorized Representative (LAR) reaches or exceeds $600 in a calendar year, BCM will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, BCM may collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email

or text notification when payments are loaded to your ClinCard. Baylor College of Medicine (BCM) and Greenphire (ClinCard Company) have entered into an agreement that requires Greenphire to protect your personal information.

BCM will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, BCM will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

This institution may use your biospecimens (even if identifiers are removed) for commercial profit, however, the institution does not plan to pay royalties (share with you in the commercial profit) to you if a commercial product is developed from any biospecimens (blood or tissue) obtained from you during this study.

Research Related Injury

For patients receiving oral iron therapy, common adverse effects (i.e. constipation) will be assessed at clinical visits, and supportive care measures (medications to assist with constipation) may be prescribed/offered as needed to patients reporting such symptoms. Regarding the most serious complication of accidental ingestion, medications will be dispensed in child-proof containers to minimize the risk. In any patients in whom accidental ingestion occurs, information and referral will be made to the TCH Emergency Department for further assessment and care.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, JACQUELYN POWERS, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: JACQUELYN M. POWERS at (832) 822-4242 during the day and after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here _____