Omega Heroes: Fatty Acid Supplements and Inflammation in children with Autism Spectrum Disorder

NCT03550209

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NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Omega Heroes: Fatty Acid Supplements and Inflammation in children with Autism Spectrum Disorder

PRINCIPAL INVESTIGATORS: Dr. Sarah Keim; Dr. Lynette Rogers

CONTACT TELEPHONE NUMBER: 614-355-2849; 1-800-792-8401, extension 52849

PARENT/LEGAL GUARDIAN'S NAME: _____

DATE OF BIRTH: _____

CHILD'S NAME: _____ **DATE OF BIRTH:** _____

Key Information About This Study

The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to find out if a fatty acid nutritional supplement oil is an effective treatment for autism spectrum disorder symptoms.

Caregivers will be asked to give their child a fatty acid nutritional supplement oil or placebo oil every day (in the morning and evening) for 3 months.
Your child will have blood drawn 3 times during participation.
Caregivers will be asked to complete some brief questionnaires.
Caregivers will complete a study diary to show if child took study treatment each day.

There will be 3 visits over 3 months at the main campus of Nationwide Children's Hospital.
First visit: 2-2.5 hours, second visit: 1 hour, third visit: 1.5 hours
We will call you five times within the 3 months of participation. One call will last longer (20-25 minutes) than the others.
See a more detailed discussion later in this form.

The main risks of the study are bleeding and bruising at the site where the blood is drawn, allergic reaction to nutritional supplement oil or placebo oil, and mild diarrhea, gas or other intestinal related symptoms associated with nutritional supplement oil or placebo oil.

You and your child may not benefit from being in this study. We hope that the information learned will help others in the future who have an autism spectrum disorder diagnosis.

If you are interested in learning more about this study, please continue reading below.

1) INTRODUCTION

This is a research study that is interested in learning about how a nutritional supplement oil may help children with Autism Spectrum Disorder (ASD). Dr. Sarah Keim and Dr. Lynette Rogers are working on this study with doctors from the Developmental and Behavioral Pediatrics Department at Nationwide Children's Hospital. We invite you to participate in this research study because your child was recently diagnosed with ASD.

Your participation in this study is voluntary. Please learn enough about this research study and its risks and benefits to decide if you agree to participate. We will explain the study to you and give you a chance to ask questions about anything you do not understand. This process is called "informed consent." It is up to you to choose if you want to be in this study. You may decline to participate in this study or quit this study at any time, and standard medical care will still be available here or at the doctor of your choice without a penalty or loss of benefits to you and your child.

Before agreeing to be in this research study, it is important that you read and understand the study information in this consent form**.** By signing this consent form, you agree to be in this study. If you choose to participate, you will be given a signed and dated copy of the consent form.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

Although at least 1 in 68 U.S. children has been diagnosed with ASD, no approved medications exist to treat the core symptoms.

Some studies have shown that children with ASD who take a nutritional supplement oil that has long chain polyunsaturated fatty acids show less hyperactivity and act out less than children who took a placebo oil. A placebo is made to look, smell, and taste like the fatty acid supplement, but does not contain the same ingredients. Fatty acids are naturally found in foods like fish. We think fatty acid nutritional supplements might have these benefits because they reduce inflammation in the body. Inflammation seems to be common in people with ASD. So, this study will look at how fatty acid nutritional supplement oil may reduce inflammation in the body.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY FAMILIES WILL TAKE PART?

This study will be done at Nationwide Children's Hospital. We hope to enroll about 66 families in this study.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

This study will last for 90 days, about 3 months.

During the study, we ask that you give your child a nutritional supplement oil or placebo oil every day, twice a day, during the study. We also ask that you come to Nationwide Children's Hospital 3 times. Visit 1 is today. Visit 2 will be 45 days later and visit 3 will be 45 days after that. If you have a visit scheduled already in any of the Nationwide Children's Hospital clinics, we will try to make the study visit the same day to make it convenient. The study visits last anywhere from 1 to about 1.5 hours.

What we ask you to do:

- During the study visits, we will ask you to answer questions about your child's diet and your family. You have the option of skipping any question you do not want to answer. We will ask you to provide us with updated contact information. We will not share this information with anyone outside the research team and we will only contact you about the study.

- During the first and last in-person visits, trained research staff will measure your child's height and weight.

- During each in-person visit, a 3mL (about half a teaspoon) blood sample will be drawn by an experienced and trained Nationwide Children's Hospital employee. The blood drawn during each visit will be used to see how much of the oil your child is taking and how the body is responding to the oil.

- At the first study visit, you will be given bottles of an oil to take home with you. We will ask you to give your child the oil each day. We will provide a paper diary and instructions for you to record that your child took the oil.

- We will check in with you a total of 5 times to see how the study is going for you. One of these phone calls will request a more detailed update than the others. We will call this phone call our "e-visit." We will provide you with our phone number and e-mail address for you to contact us with any concerns or questions. During the follow up calls, study staff will request photos of complete study diary pages on occasion. These photos can be texted or emailed on the day of the follow up call.

To check to see if the fatty acids help children with ASD and to see what the best dose is, we need different groups of families. To determine which group each family is in, this study is randomized. The word "randomized" means that each family will be picked by chance, like tossing a coin or drawing straws, to receive a low, medium, or higher dose of the fatty acid supplement oil or placebo oil. By randomizing families into one of the groups, we can check in a fair way to see if the nutritional supplement helps children with ASD.

One group will receive the nutritional supplement which is a liquid that contains oil from fish and oil from a plant called borage. The fatty acids in this liquid are naturally occurring and are found in breast milk and foods like chicken, fish, and cooking oils. The other group will receive a placebo liquid which contains canola oil, a common cooking oil. The nutritional supplement and placebo contain a small amount of lemon to make them taste good. There are no known benefits of the placebo oil. Both the nutritional supplement oil and placebo oil look, smell, and taste the same.

This study is blinded. Blinded means you and all the staff involved in the study will not know who is receiving the nutritional supplement oil or the placebo oil. However, in the case of a medical emergency, there is a way for the study staff to quickly find out which one a child is receiving.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study. It is possible that you could feel upset when answering questions about your and your child's well-being and health, but it is more likely that you find the questions or feedback process a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to.

Although the nutritional supplement oil and placebo oil used in this study are available to buy over-the-counter in local stores, all nutritional supplements or oils may cause side effects or allergic reactions. There is no way to predict whether your child will have any side effects.

Common side effects may include mild cases of diarrhea, gas or other intestinal related symptoms. Allergic reactions can happen with any nutritional supplement. Symptoms of an allergic reaction can include rash, itching, hives, headache, stomach discomfort, or difficulty breathing. Because of this, children with a fish, canola, or borage seed allergy are not eligible to participate. Allergic reactions can be severe and possibly life threatening. Severe allergic reactions are a rare possibility.

An experienced employee will draw a small amount of blood and will work to make this as painless as possible for your child. The physical risks of drawing blood by placing a needle in a vein may cause

pain, lightheadedness, bleeding, bruising, or swelling at the puncture site. Infection is a rare possibility.

If any of the symptoms listed above are severe, you must get medical help right away. If you are worried about anything while in this study, please call the Principal Investigator, Study Doctor, or Study Coordinator. The contact information is listed on Section 16.

Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.

There may be other risks of being in this research study, which are not known at this time.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Although there may be no direct benefit to you from being in this study, we might learn something that could help other children with ASD and their families in the future.

7) WHAT OTHER OPTIONS ARE THERE?

Your participation in this study is voluntary. It is not necessary to participate in this study in order for you to get care for your child's condition.

8) WILL THERE BE ANY COSTS TO ME?

It will not cost you anything to be in this study. We will not bill you or your insurance company for the study. For your time and inconvenience, you will be compensated $75 at the end of each of the 3 in-person study visits. In addition, we will give you $2 every time you return a study diary (up to $14 total if all diaries are returned) to thank you for your time and effort. We will pay for your parking in the Children's Hospital Parking Garage during your study visits. We also will give your child a book or toy to take home at the completion of each study visit. If you complete all study visits and the e-visit phone call, you will be compensated an additional $20 at the end of the final visit.

In regards to your compensation, Nationwide Children's Hospital is now using a service called ClinCard® by the company Greenphire to manage payments for study participation. You will no longer be receiving compensation in cash, check, or by gift card.

You will be issued a ClinCard® debit card specially designed for clinical research. When each study visit is completed, funds will be approved and automatically loaded onto your card. The funds will be available immediately after being loaded, but could take up to 1-2 business days. These funds can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, please call the study coordinator for a replacement card.

Your name, subject number, address, email address, cell phone number and social security number will be collected by Nationwide Children's Hospital in order to issue the debit cards. Debit cards are managed by Greenphire Inc. All information is stored in a secure fashion. Your information will not be shared with any third parties and will be kept completely confidential.

If you receive $600 or more in a calendar year from participating in research studies, you will be issued a 1099 IRS Form to file with your income taxes.

9) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

If your child is hurt by the nutritional supplement oil or placebo oil or the procedures that are part of the study, you should seek medical treatment for the injuries and tell the Principal Investigator or Study Doctor as soon as possible. See the phone number listed in Section 15 of this form. If it is an emergency, call 911 or go to the nearest emergency department.

In most cases, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study. If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

10) WHAT WILL HAPPEN IF NEW INFORMATION IS FOUND OUT ABOUT THE DRUG OR TREATMENT?

If new information is found out during this study that might change your mind about participating or might affect your child's health, a study staff member will discuss it with you as soon as possible.

11) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in the study at any time. If you decide to stop being in this study, you must call the Principal Investigator or the Study Coordinator. If you stop being in the study, there will not be a penalty or loss of benefits to which you are otherwise entitled. The Principal Investigator will talk to you about any medical issues regarding stopping.

If at any time the Principal Investigator or Study Doctor believes participating in this study is not the best choice of care, the study may be stopped and other care prescribed. If the study instructions are not followed, participation in the study also may be stopped. If unexpected medical problems come up, study staff may decide to stop your participation in the study.

12) OTHER IMPORTANT INFORMATION

It is important that health care providers know about all medicines that your child is taking. This includes the nutritional supplement oil being tested in this research study. Because of this, we may inform your primary care doctor (if you have one) that your child is participating in this study and document his/her participation in this study in your Nationwide Children's Hospital medical record. This is done so extra care can be taken in prescribing other medicines and looking at any unexplained symptoms that may occur.

Primary Care Physician Contact Info:

Name: _____

Location (City, State): _____

Phone Number (including area code): _____

Being in more than one research study at the same time may cause injury. Please tell us if you are in any other research study so a decision can be made about being in more than one study at the same time. We may need to notify the other study team to see if you can participate in this study.

If you are an employee at Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job performance or appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. A final study summary will be available on the *http://www.ClinicalTrials.gov* website.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

If study staff observes something that makes us concerned for your welfare or the welfare of your child, we may not be able to keep that information private and will contact the appropriate authorities.

13) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study may include information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to Dr. Sarah Keim and Dr. Lynette Rogers and their study staff to collect, use, and disclose your PHI for this research study unless otherwise allowed by applicable laws. Every effort will be made to keep your PHI private. Your PHI will be removed or coded (de-identified) as much as possible to protect your privacy. Information collected is the property of the Principal Investigators. In the event of any publication regarding this study, your identity will not be revealed.

If you have a bad outcome or adverse event from being in this study, the Principal Investigators and staff or other health care providers may need to look at your entire medical record.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time.

PHI that may be used or disclosed may include demographic information such as names, addresses, telephone numbers; medical diagnoses, dates such as admission/discharge and birthdate; and identifying numbers such as medical records number.

Some of the people or companies that may be authorized to use, disclose, and receive PHI collected or created by this research study include:

- The Principal Investigators, Study Doctor, and the study staff
- Representatives of the Office for Human Research Protections, the federal government office that oversees human subject research
- Members of Nationwide Children's Hospital Institutional Review Board (IRB), a committee that reviews all human subjects research for Nationwide Children's Hospital.
- Nationwide Children's Hospital internal auditors
- The Food and Drug Administration (FDA)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may no longer be protected by federal privacy rules.

However, every effort will be made to keep your PHI private. Your PHI will be removed or coded (de-identified) as much as possible to protect your privacy.

Your PHI may be used to access medical charts and/or to contact you in the future.

You may decide not to authorize the use and disclosure of your PHI. However, if it is necessary for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may also withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports. Please address this request to:

Sarah Keim, PhD, MA, MS
The Research Institute at Nationwide Children's Hospital
Center for Biobehavioral Health
700 Children's Drive
Columbus, Ohio 43205

14) STORED SAMPLES

Sometimes, a small amount of blood may be leftover from the study and stored for research at a later time, perhaps even years from now.

With your permission, we would like to store any leftover study samples and information related to such samples (diagnosis, age at diagnosis, etc.) for research that may be performed in the future. Any unused samples will be stored for an indefinite amount of time. Information related to the samples may or may not include personal identifiers, such as your name, address, etc. There could be widespread sharing of these samples and associated information, but an Institutional Review Board, which protects the rights, welfare, and safety of human research subjects, will review and approve each new project.

Use of your samples for future research may help researchers learn more about how to prevent, find, and treat various diseases and conditions, even diseases and conditions that are different from yours. Genetic material (such as DNA and RNA) may be removed from the stored samples and used for genetic testing, which could uncover information about your inherited traits.

Using your samples for future research will probably not help you. You will not be told the results of any future research. Your doctor will also not be told the results of any future research.

Your samples and information will be used only for research and will not be sold. There is a possibility that future research may lead to development of products that will be sold to the public. If this happens, there is no plan to share any financial gain with you.

The results from this future research may be published but your identity will not be revealed.

If you decide at any time that you do not want your samples or related information stored for future research, you must make this request in writing to the Principal Investigator.

Once we receive your written request, we will destroy your samples and related information. However, once your samples and related information have been de-identified, we will not be able to destroy them because we will not be able to link your samples or information back to you. Also, if

we have already shared your samples or information with another individual or entity, we will not be able to destroy any of the samples or information that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage of the samples or related information at any time and destroy the samples or information without sending notice to you or obtaining your consent.

You do not have to agree to use of your samples or related information for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my samples and related information to be stored and used for future research as described above: (initial your choice)

_____ YES _____ NO

15) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about anything while on this study, you have access to talk to the Principal Investigators, Study Doctor, or the Study Coordinator. Contact information is located in Section 16 of this document.

If you have questions, concerns or complaints about the research, questions about your rights as a research volunteer, cannot reach the Principal Investigators or Study Doctor, or want to call someone else, please call The Nationwide Children's Hospital Institutional Review Board, (IRB, a committee that reviews all human research) at (614) 722-2708.

16) IMPORTANT CONTACT INFORMATION

Principal Investigator:
Sarah A. Keim, Ph.D.
Center for Biobehavioral Health
The Research Institute
Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205
Telephone: 614-355-2849 or 1-800-792-8401, extension 52849
Email: Sarah.Keim@NationwideChildrens.org

Principal Investigator:
Lynette K. Rogers, Ph.D.
Center for Perinatal Reserch
The Research Institute
Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205
Telephone: 614-355-2849 or 1-800-792-8401, extension 52849
Email: Lynette.Rogers@NationwideChildrens.org

Study Doctor:
Daniel L. Coury, MD
Division of Developmental and Behavioral Pediatrics
Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205
Telephone: 614-355-2894 or 1-800-792-8401, extension 52849
Email: Daniel.Coury@NationwideChildrens.org

Study Coordinator:
Katie Smith, BS
Center for Biobehavioral Health
The Research Institute Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205
Telephone: 614-355-2849 or 1-800-792-8401, extension 52849
Email: Katie.Smith@NationwideChildrens.org

PARENT/LEGAL GUARDIAN'S NAME: _____ **DATE OF BIRTH:** _____

CHILD'S NAME: _____ **DATE OF BIRTH:** _____

PARTICIPANT OR PARTICIPANT'S PARENT OR PERSON AUTHORIZED TO CONSENT ON BEHALF OF THE CHILD (PARTICIPANT TO THE PARTICIPANT'S GENERAL MEDICAL CARE)

I have read this consent form and have had a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about participation in this study or a research-related injury, I may contact the Principal Investigator. By signing this consent form, I certify that all health information I have given is true and correct to the best of my knowledge.

I have been given a copy of the Nationwide Children's Hospital Notice of Privacy Practices. I understand that my right to my patient information that is created or collected by Nationwide Children's Hospital in the course of this research can be temporarily suspended for as long as the research is in progress. I also understand that my right to access will be reinstated upon completion of this research unless I have been told by the Principal Investigator that I will not receive study results.

I agree to participate in this study and I give permission for my child to participate in this study. I will be given a copy of this consent form with all the signatures for my own records.

CONSENT SIGNATURES

_____ _____

PARTICIPANT or PARTICIPANT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

_____ _____

PARTICIPANT or PARTICIPANT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

Permission of the second parent not obtained because (select all that apply):

_____ Not required by the IRB (risk level 1 or 2).
_____ Other parent is deceased.
_____ Other parent is unknown.
_____ Other parent is not reasonably available.
_____ Only one parent has legal responsibility for the care and custody of subject.

Investigator/Research Staff

I certify that I have explained the research, its purposes, and the procedures to the child's legal representative (e.g., parent) before requesting the signature above.

_____ _____

PERSON OBTAINING CONSENT **DATE & TIME AM/PM**