NCT04417595
Smoking Cessation in Pregnancy (INFANTS)
2/6/2024

Study Title:	Investigating N-3 Fatty Acids for Preventing Neonatal Tobacco-related outcomeS (INFANTS) Study
Version Date:	02/16/2023
PI:	Harvey J. Murff, MD, MPH

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
Vanderbilt University Medical Center (VUMC) is doing a research study called **Investigating N-3 Fatty Acids for Preventing Neonatal Tobacco-related outcomeS (INFANTS) Study.** It is being funded by the National Institutes of Health (NIH). The purpose of the INFANTS study is to determine if fish oil capsules might prevent early labor and help pregnant women smoke fewer cigarettes or quit smoking entirely. The study will also evaluate how fish oil supplementation affects nicotine cravings. We would like to enroll 400 participants for this study.

Your participation in the study will last up to 40 weeks. During the study you will be asked to take the study medication daily. This medication will be either a fish oil supplement or an olive oil supplement. Over the study time, you will have two in-person study visits which will occur before or after you see your obstetrician in their office. At these two in person clinic visits you will be asked to complete a brief questionnaire and provide a sample of blood and an expired carbon monoxide (CO) sample. After your initial visit, you will be contacted by a tobacco-cessation specialist at Vanderbilt University Medical Center to help you quit smoking. Every two weeks until you deliver your baby, study staff will text, call, or email (your choice) you to remind you about upcoming doctors' appointments and taking study medication. About 6 weeks after delivery, we will contact you to complete a brief survey about your smoking habits.

There are no direct benefits to you for taking part in this study. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Fish oil and olive oil are known to be safe in pregnancy.

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are a healthy, pregnant woman who is currently smoking cigarettes.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
Most people tolerate oil supplements well. Some people who take fish oil supplements may have increased belching, changes in how things taste and heartburn. These side effects can be minimized by keeping the study medication in the refrigerator and taking it with meals and while the capsule is cold. Large doses can also cause bloating and diarrhea. You will be asked to report any symptoms or side effects that you may be having.

Fish oil supplements are considered safe in pregnancy.

Possible small risks associated with having your blood drawn include minimal pain or bruising at the site of needle insertion, bleeding, a small chance of infection, or fainting. There are no known serious adverse effects from the exhaled carbon monoxide test.

Completing the questionnaires can take time and some of the questions could potentially make you feel uncomfortable.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:

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The benefits to science and humankind that might result from this study: Your taking part may provide information on dietary nutrients which might help individuals reduce or quit smoking while pregnant or reduce the chance of having a premature baby.

Procedures to be followed:
You will be asked to complete 2 in-person visits and a phone interview 6 weeks after delivery. In addition, a tobacco coach will contact you for help in quitting smoking, and study staff will check in with you regularly.

First in-person visit: In the first visit, you will be randomized to receiving either fish oil or olive oil capsules. Neither study staff nor you will know which one you will receive, and the choice will be made randomly, meaning you will have a 50:50 chance (like a coin flip) of receiving one or the other. During this visit, you will complete a questionnaire (plus an optional bonus exercise), have a blood draw of about 20 milliliters (mL) of blood (a little more than a tablespoon). You will also blow into a tube to measure the amount of carbon monoxide in your breath. We will also provide you with a paper guide to quitting smoking. At this visit, you will either be given or mailed a 3-month supply of study medication. If the medication is mailed to your home, it should arrive within about 2 days of this initial visit. During the study you will take 4 capsules a day for each day while on the study. Over the first three days we will have you build up the dose. On the first day you will take 2 capsules a day, on the second day you will take 3 capsules a day, on the third day you will take 4 capsules a day and remain on this dose through the study. You can take all four capsules at one time or over the course of the day. You should take the capsules with meals. You should also keep the capsules in the refrigerator if possible, to reduce potential side effects, although this is not required. You will be given a capsule diary to take home to help keep track of your medication use.

You will be called approximately one week after the first visit by one of the study tobacco treatment coaches to help you stop smoking. This call may last about 15-30 minutes.

Until you deliver your baby, study staff will contact you about every 2 weeks by phone, text, or email (your choice) to remind you about upcoming appointments and taking study medication.

Second in-person visit: You will have your second in-person study visit in about 12 weeks, right before or right after the appointment with your obstetrician. During this visit, you will complete a brief questionnaire similar to the one from your first visit (plus an optional bonus exercise), have a blood draw of about 20 milliliters (mL) of blood (a little more than a tablespoon), and have a breath test for carbon monoxide. If necessary, you will be given additional study medication. If you are unable to

complete the survey in person, we may send you a link via text or email (your choice) to complete the survey.

Delivery Information: After you deliver, we will contact the hospital where you delivered to obtain medical records from you and your baby. We will collect information related to the gestational age at delivery, any complications during delivery and the health of your new baby.

6-week post-delivery communication: Approximately 6 weeks after delivery, we will contact you by phone, text, or email (your choice) to complete a brief questionnaire (plus an optional bonus exercise).

Bonus exercise: At the first in-person visit, second in-person visit, and 6-week post-delivery communication, you will have the option of completing a two-part online exercise. In this exercise, you will be shown a series of paid tasks, such as repeatedly pressing a button on the screen or solving a puzzle. You will decide how much of each task you would like to do for the stated pay rate. This can be zero work or up to approximately 30 minutes of work for each task. At the end of the exercise, one task will be randomly chosen, and you will do the amount of work that you stated you would do for that task, for the stated payment.

Payments for your time spent taking part in this study or expenses:
You will be paid $125 for each of the two in-person study visits if you complete all study related tasks (questionnaire, blood draw, breath test, and bonus exercise). We will also pay you $50 for completing all parts of the 6-week post-delivery survey (including the bonus exercise). You could be paid up to $300 in total for your full participation in this study. In addition, through the bonus exercise, you could earn up to $150 extra ($50 per survey round) based on (a) how much work you are willing to do on the tasks in the exercise and (b) which tasks are randomly chosen for you to do.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

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There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the Principal Investigator Dr. Harvey Murff, Dr. Hilary Tindle or Elizabeth Habell at 629-395-6784.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
You will be taken out of the study if you are not able to provide the blood or unable to take the study medications. If you are taken out of the study, you will be told the reason why.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Confidentiality:
As part of this study, we will store all of your research records in secure locations. Paper copies of documents will be stored in locked file cabinets within Vanderbilt University. Only Dr. Murff and his research staff will have keys to access these files. Electronic files will be stored in a database that can only be accessed with a specific password. Only Dr. Murff and his research staff will have a copy of this password. Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt and Dr. Murff and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

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This study is supported from the National Institutes of Health (NIH). As such, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:
The results of this study will be shared through publication in journal articles. In addition, all results will be posted on an on-line data repository (Clinical.trials.gov) which is accessible by the general public. We will not be contacting you directly with the results of the study.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

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Who will see, use, or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Murff in writing and let him know that you withdraw your consent. His mailing address is 2525 West End Avenue Suite 450, Nashville, TN 37203. At that time, we will stop getting any more data about you. However, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____

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OPTIONAL STUDY ACTIVITIES

You can choose to take part in the additional studies listed below. Things to know about these studies:

- They are optional. You can still take part in the main study even if you say "no" to any or all of these studies.
- These studies will not help you or your child directly. We hope the study results will help other people in the future.
- Taking part in the optional studies of any tests done on your samples will not cost you anything.
- If you agree to the optional sample collection and testing for you, the collected samples will be treated like the rest of the samples and testing involved in this study.

Consent for Optional Future Research Studies

I agree to be contacted in the future as a follow-up to this study or for future studies.

☐ Yes ☐ No

I agree to be contacted regarding my child in the future as a follow-up to this study or for future studies.

☐ Yes ☐ No

Consent for Optional Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give blood for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.]

If you agree, we will obtain the DNA from blood that was already collected as part of the study. There would be no inconvenience or discomfort to you.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

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To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Murff and his study staff will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact Dr. Murff at 615-936-8319 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we may not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please initial "Yes" or "No" to each of the following items:

My blood may be used for gene research in this study.

☐ Yes ☐ No

My blood may be stored/shared for future gene research in immunology, obstetrics, and metabolic conditions.

☐ Yes ☐ No

My blood may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

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☐ Yes ☐ No

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

Time: _____