Fasting Versus Fed: Effect of Oral Intake Prior to the Glucose Tolerance Test in Pregnancy

Informed Consent Form

NCT04547023

March 15, 2021

IRB Use Only
Approval Date: March 15, 2021
Expiration Date: (Does not Expire)

Are you participating in any other research studies? Yes_____ No_____

FOR QUESTIONS ABOUT THE STUDY, CONTACT:
Yair Blumenfeld, MD
Department of Obstetrics and Gynecology
453 Quarry Rd.
Stanford, CA, 94305
(650) 725-5720

DESCRIPTION: You are invited to participate in a research study on gestational diabetes (GDM). GDM affects up to 9% of pregnancies and is associated with a higher risk of cesarean delivery and high blood pressure in pregnancy. GDM increases the risk of giving birth to a large infant and also birth trauma. Patients who are diagnosed with GDM are also at an increased risk of being diagnosed with type 2 diabetes later in life. Every pregnant woman is screened for GDM, and you have been selected as a participant because you are pregnant and will undergo the screening test as part of normal standard of care. We expect to enroll 200 participants into this study, with all recruitments done here at Stanford.

GDM screening as part of your standard of care is typically performed using a 1 hour oral glucose tolerance test between 24-28 weeks of gestation. In this test, the patient drinks a beverage with 50 grams of glucose. **This test is traditionally recommended to be performed without regard to the time of day or a patient's last meal**. One hour after ingesting the drink, a blood draw is performed to measure glucose levels in the blood. If the glucose level is normal, the patient does not have GDM. If the glucose level is elevated (glucose $\geq$ 140 mg/dL), this is considered to be a positive screen. It will then be recommended that you have a 3 hour oral glucose tolerance test to confirm the diagnosis of GDM. These are all part of your standard of care.

In this study we hope to determine how the time interval between the last meal and the GDM screen affects the screening result. If you choose to participate in the study, you will be assigned to 1 of 2 groups that will be determined using an online randomization tool:

1) The 1st group will be asked to NOT eat or drink (except for water) for at least 6 hours prior to the 1 hour oral glucose tolerance test.
2) The 2nd group will be asked to eat (without restriction) within 2 hour of the 1 hour oral glucose tolerance test.

There is a 50% chance for you to be assigned to either of the two groups.

As a part of the study, you will also be asked to complete a quick online or telephone survey to describe the timing and content of your last meal prior to the test. Your and your baby's medical records will also be reviewed.

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This research will not include whole any genetic testing including genome sequencing.

Future use of Private Information and/or Specimens
Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Your specimens will be not be stored, however, the data regarding the results of your blood glucose tests will be stored.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

RISKS AND BENEFITS: The risks associated with this study are discomfort from obtaining a blood draw at the venipuncture site. A blood draw is a part of the standard GDM screen and all pregnant women, those participating and those not participating in the study, undergo a blood draw as a part of GDM screening. There may be redness at the site of the draw. Very rarely, there is the risk of a potential infection.

In addition, the glucose drink may rarely cause nausea, vomiting, abdominal bloating, and/or headache.

GDM screening is performed in all pregnancies, but there is lack of knowledge about the effect of oral intake or fasting on the GDM screen. While we cannot and do not guarantee or promise that you will receive any benefits from this study, we hope that your participation will benefit pregnant women in the future. Specifically, once we learn the effect of the fasting vs the fed state prior to the GDM screening, we will be able to ensure that the test is being appropriately administered to pregnant women in the future.

Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: Your participation in this experiment will take approximately 1-7 hours. This time includes the time that will be required to fast prior to the test as well as waiting an hour after drinking the 50 gram glucose beverage before the blood draw. There will also be a 5 minute survey after completion of the test.

PAYMENTS/REIMBURSEMENTS: You will receive a $15 gift card as payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw

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your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

You have the right to refuse to answer particular questions.

National Institutes of Health is providing funding support.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health (NIH) which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

CLINICALTRIALS.GOV

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.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your baby's health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your and your baby's health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of the study is to investigate if the timing from last oral intake prior to the screening 1 hour oral glucose tolerance test for gestational diabetes affects the number of people who screen positive. Your and your baby's information will also be used to analyze maternal and neonatal outcomes in relation to the result of the 1 hour oral glucose tolerance test. The aim is for publication of the study into an obstetrical journal.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your and your baby's health information (and to discontinue any other participation in the study) at any time. After any revocation, your and your baby's health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your and your baby's health information in this study, you must write to:

Yair Blumenfeld, MD
453 Quarry Rd.

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Stanford, CA, 94305

What Personal Information Will Be Obtained, Used or Disclosed?
Your and your baby's health information related to this study may be used or disclosed in connection with this research study including your and your baby's name, medical record numbers, telephone number, address, electronic mail addresses and dates of birth. We will also collect demographics, obstetrical and prenatal history, past medical history, clinical narratives, prescription/ medications, laboratory and imaging test results, obstetric outcomes, antepartum, delivery and postpartum data/ complications, and neonatal outcome data/ complications. Dates of service will also be collected.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director – Yair Blumenfeld, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institutes of Health
- Stanford Diabetes Research Center (SDRC)

Your and your baby's information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your and your baby's health information will end on July 1, 2050 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

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WITHDRAWAL FROM STUDY:
The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You have pregestational diabetes or have been taking medications for glycemic control in the past
- You have taken steroids within 7 days of the 1 hour oral glucose tolerance test or have taken an oral steroid daily for over 4 weeks in the past year
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:
If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Yair Blumenfeld, MD at (650) 725-5720. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Yair Blumenfeld, MD at (650) 725-5720.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Meryl Sperling, MD at (310) 663-1211.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;

- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

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The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____

Signature of Witness Date

_____

Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options* presented *by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*