INFORMED CONSENT DOCUMENT

David Grant USAF Medical Center
101 Bodin Circle
Travis Air Force Base, CA 94535

TITLE OF STUDY

Unrestricted Low Fat, Low Residue Oral Intake during Labor: A Randomized Controlled Study

CONTACT INFORMATION

Role	Name	Dept.	Phone#
Principal Investigator	Maj Jeanette Anderson	AFMOA/SGNP	210-395-9320
Other Contacts:			
Co-Principal Investigator	Capt Dawn Morales	Labor and Delivery	707-423-3619
Patient Advocate	Mark Lane	Patient Relations	707-423-2388
Director, Clinical Investigations	Lt Col Patrick W. Kennedy	Clinical Investigation	707-423-7400

PURPOSE OF STUDY

Because you are a healthy pregnant women with an assessment of low risk for complications during labor, over the age of 18 and plan to labor/deliver at DGMC you are asked to consider participation in a research study at David Grant USAF Medical Center. The study is titled "Unrestricted Low Fat, Low Residue Oral Intake during Labor: A Randomized Controlled Study".

Participating in research is voluntary. You have the right to know about the procedures, risks, and benefits of the research study. If you decide to take part, you can change your mind later and leave the study. To participate in this study, you will need to give your written consent by signing this form. Please take your time to make your decision and discuss it with your family, friends, and caregivers.

Currently women are not allowed to eat during labor due to fears that during labor a woman could inhale her own vomit. This is due to a recommendation from the 1940s when general anesthesia was commonly used during labor. In order to anesthetize a patient, intubation was used. Intubation, is the placement of a flexible plastic tube into the trachea (windpipe) to serve as a conduit through which to administer certain drugs. The worry was that intubation may cause a patient to gag and vomit and then inhale the vomit, this is called aspiration and it can be fatal. However, since that time, anesthesia medications and methods have evolved significantly and general anesthesia is no longer routinely used. Although general anesthesia use is not common, the practice of restricting oral food and fluid intake is still adhered to in many U.S. hospitals.

The purpose of the study is to evaluate the health of newborns and mothers and mother's satisfaction with the labor experience at David Grant Medical Center when mothers are allowed unrestricted low fat, low residue food choices during labor.

This study will enroll 200 subjects over a period of two years.

You are being asked to take part in this study because you have sought care and intend to give birth at the David Grant Medical Center.

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You will not be asked to make additional visits during your participation above those already scheduled due to your pregnancy.

PROCEDURES

As a participant, you will be randomized to one of two groups described below. "Randomized" means that you are put into a group by a selection similar to flipping a coin. You will have an equal chance of being assigned to either of the groups.

There will be two groups of subjects. The first is called the control group. The control group will receive normal care and be allowed to consume a clear liquid during active labor. The second group is called the intervention or experimental group. The intervention or experimental group will be allowed to eat low fat, low residue foods such as lean protein, fruits, vegetables, and low-fat dairy. Labor & Delivery (L&D) staff will record intake after each meal.

The staff will ask you about your feelings of nausea or vomiting. The staff will also record how long you are in labor, how you deliver (spontaneous vaginal birth, operative vaginal birth, or cesarean birth), if you aspirate (inhale vomit), and your baby's Apgar score. An Apgar score is a number given to a baby at one and five minutes after birth. The 1-minute score determines how well the baby tolerated the birthing process. The 5-minute score tells the providers how well the baby is doing outside the mother's womb.

Lastly a single question will be asked of you regarding your satisfaction with your labor and childbirth experience at David Grant Medical Center.

If as a result of participating in this research study your provider finds it necessary for you to have a procedure requiring additional informed consent, a separate informed consent document will be completed at the time of the procedure.

RISKS/INCONVENIENCES

Many of the known risks of participating in this study are also associated with a normal labor.

It is likely that you will experience:
Increased nausea
Increased vomiting
A larger bowel movement due to eating

It is less likely that you may experience:
Participation may add additional time to the overall length of labor
Increased rate of cesarean deliveries

There are rare, but serious risks which may include:
Pulmonary aspiration which is when food, liquids, saliva, or vomit is breathed into the airways.
Pulmonary aspiration may lead to pneumonia or death by suffocation.
Symptoms include coughing, difficulty breathing, and in some cases choking.

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In the rare event that you experience pulmonary aspiration, you may have difficulty breathing or choking which could lead to less oxygen for your baby

While we will take every precaution we are able to protect your information, there is a small risk of a confidentiality breach. Your data will be stored on a David Grant USAF Medical Center computer. That data will be password protected on a common access card enabled computer. Lastly, the computer that we will access your data from will be located in a locked office.

BENEFITS

This research study is intended to benefit you, military beneficiaries, and the medical community in general, by supplying important information that will improve care and satisfaction during labor for all pregnant women.

This study may also benefit others by helping to find out whether this treatment is better than others available for managing the labor process.

COSTS

There are no additional costs to you for participating in this study.

PAYMENT

You will not receive any compensation for participating in this study. You will not be compensated for travel expenses.

ALTERNATIVES

Choosing not to participate is an alternative to participating in this study. You may speak with your provider about alternative treatments available.

EVENT OF INJURY

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations. If you have questions about your rights or if you believe you have received a research-related injury, you may contact the Director of the Clinical Investigation Facility at 707-413-7400, the Patient Advocate at 707-423-2388, or the study investigator at 707-423-3619.

IF YOU ARE A VETERAN

If you are injured as a result of taking part in this study, you will receive medical treatment at this facility at no cost to you, provided that such treatment can be provided at this facility.

Although the cost of the experimental treatment provided in this study will be provided at no cost to you and your insurance will not be billed, be aware that Veterans Affairs may not pay for experimental treatments or any procedures, medications or treatment outside of the scope of standard or normal treatments. Additionally, later treatment resulting from certain complications or outcomes may not be covered by the Veterans Affairs. Some Veterans are required to pay co-payments for medical care and services provided by Veterans Affairs. These co-

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payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.

In the event that you require care outside of this facility or a Veterans Affairs facility, you and/or your health plan will be charged for such treatment. The study organizers have no policy or plan to pay for such medical treatment.

OCCURRENCE OF UNANTICIPATED ADVERSE EVENT

If an unanticipated event occurs during your participation in this study, you will be informed immediately. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin, or your medical agent who has legal authority to make medical decisions on your behalf. If you wish to specify a medical agent, you should provide a medical power of attorney, a document which appoints an agent. Contact the Office of the Medical Law Consultant at 707-423-7836 if you have questions about a medical power of attorney.

WITHDRAWAL

The study investigator may decide to withdraw you from the study if he or she believes it is in your best interest. You may also withdraw at any time without penalty or loss of benefits. If you decide to discontinue the study, contact the Primary Investigator or your provider for instructions on how to do so safely. In the event you are withdrawn from the study by the study staff or care provider, you will not receive food during your labor.

PRIVACY AND CONFIDENTIALITY

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Note: Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities. Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, the David Grant Medical Center Institutional Review Board.

Records of your participation in this study may only be disclosed according to Federal law, including the Federal Privacy Act, 5 U.S.C. 552a; the Health Insurance Portability and Accountability Act (HIPAA); and the Freedom of Information Act, 5 U.S.C. Sec 522, and their applicable regulations.

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.

Upon the close of the study all records will be transferred to the Clinical Investigations Facility for storage for six years.

DECISION TO PARTICIPATE

The decision to participate in this study is completely voluntary on your part. Refusal to participate in the research study will involve no penalty or loss of benefits. No one has coerced or intimidated you into participating in this program. You are participating because you want to. Your investigator(s) has adequately answered any and all questions you have about this study, your participation, and the procedures involved. You understand that the investigator will be available to answer any questions concerning procedures throughout this study. You understand that if significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed. You further understand that you may withdraw this consent at any time and discontinue further participation in this study without prejudice to your entitlement to care. You also understand that the investigator of this study may terminate your participation in this study at any time if the investigator feels this to be in your best interest. You will be provided a copy of this consent form. Your signature below indicates your willingness to participate in this research study and serves as your consent to release your protected health information.

CONSENT FOR ADULT PARTICIPANTS

Research Participant:
I have read this consent form and have been given the chance to ask questions. I agree to participate in the research described above, entitled: **Unrestricted Low Fat, Low Residue Oral Intake During Labor: A Randomized Controlled Study**

Printed Name: _____

Signature: _____ Date: _____

Principal Investigator (or Associate Investigator, or IRB-Approved Study Staff):
I have given this research participant (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The participant has indicated that he or she understands the nature of the study and the risks and benefits of participating, and consents to participate.

Printed Name: _____

Signature: _____ Date: _____

WITNESS:

Printed Name: _____

Signature: _____ Date: _____