UT Austin IRB Approved
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Consent to Participate in Research

Basic Study Information

Title of the Project: Study of nUtrition in Postpartum and EaRly life (SUPER) Feeding Study
Principal Investigator: Marissa Burgermaster PhD, The University of Texas at Austin
Study funding source: National Cattlemen's Beef Association – Beef Checkoff

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to learn whether there are different effects of beef and plant-based beef on (a) breastmilk composition, particularly fatty acids; (b) maternal glycemic control; (c) maternal satiety; (d) infant breastmilk intake; and (e) mothers' weight.
- In order to participate, you must be a woman with a 6-12 week old infant who is exclusively breastfeeding.
- If you choose to participate, you will be asked to eat the meals and snacks provided to you for 12 days over about a 3-week period.
- During the duration of this study, the following measures will be collected:
    - Breastmilk composition – you will collect 3 breast milk samples daily
    - Daily food intake measured via menu check-off, photos, and/or dietary recalls or records.
    - Satiety
    - Blood sugar monitoring with the continuous glucose monitors
- Throughout the study, you will be asked to come to Dell Pediatric Research Institute for 6 study visits (including today). If you decide to join the study, today, we will
    - Give you a breast pump to collect breast milk samples
    - Fit you with a continuous glucose monitor
    - Measure your body weight and height
    - Perform a weighed feeding of your infant to measure breastmilk intake
    - Gather survey information
- At subsequent study visits, you will return breastmilk samples and have your CGM replaced once. We will also ask you information about physical activity, digestive symptoms, and your baby's appetite and feeding behavior. At two study visits we will take your weight and perform a weighed infant feeding again.
- Risks or discomforts from this research are generally not greater than everyday life. However, there is some risk of discomfort associated with monitoring procedures.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

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What is the study about and why are we doing it?

The first months of life are a vital time to establish health trajectory of both an infant and mother. It is important that guidance provided to new families be based on the most rigorous scientific evidence possible. Beef is a particularly nutrient-complete package for lactating women. However, plant-based beef products have similar nutrient profiles, and many consumers believe that they are a healthier alternative to beef. The goal of this study is to understand the different effects that beef vs. plant-based beef have on (a) breastmilk composition, particularly fatty acids; (b) maternal glycemic control; (c) maternal intake and satiety; (d) infant intake

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to complete the following procedures:

Orientation: Dell Pediatric Research Institute (DPRI): Approx. 2 hours

- *During this meeting you will complete:*
  - **Body Weight**: This will be measured to the nearest 0.1 kg using a research scale, similar to a scale you might use at home to weigh yourself.
  - **Body Height**: This will be measured to the nearest cm using a research stadiometer, which is a wall-mounted ruler.
  - **Food and Life Questionnaire:** You will complete a questionnaire about food you consume and factors in your life that are related to food. These will take approximately 15 minutes to complete.
  - **Breastpump.** You will be given a manual breast pump and instructed how to use it to collect breastmilk samples for the study during orientation. You will also be provided containers with labels to collect the samples and indicate the time, date, and your participant ID on the labels. You will also provide a breastmilk sample to the research team at this time.
  - **Continuous Glucose Monitor**: For the duration of the study, we will ask you to wear a continuous glucose monitor (CGM) to measure how your blood sugar levels change over the day in a free-living environment (at home/work, not in our clinic). The CGM is the type that patients with Type 1 Diabetes often use to monitor their glucose levels over the course of the day. The CGM can be worn on the arm or abdomen. We will clean the area and then will affix the CGM to your skin. The CGM places a small filament under your skin. The insertion is quick and typically painless, though you might feel a slight pinch. Adhesive will hold it in place while you wear it and you will be able to engage in your normal activities while wearing it. It will be affixed to a device that will measure and record your glucose levels throughout the day. You will not see your blood glucose levels at any point during the study.
  - **Beef or Plant-Based Beef Assignment**: You will be randomly assigned (like the flip of a coin) to receive either meals containing beef or meals containing plant-based beef. You have a 1 in 2 chance of receiving either condition in the first part of the study. You will be assigned the other meals in the second part of the study. The only difference between the beef condition and plant-based beef condition is whether the meat contained in the meal is beef or plant-based beef. All other components of the recipes and packouts are the same. The recipes have been developed by a research chef to ensure that they will meet the nutritional needs of lactating women.
  - **Weighed Feeding*:*** We will weigh your infant unclothed on a digital scale. You will then breastfeed your baby until your baby is finished, We will give you

privacy for this. Once your baby finishes the feeding, we will again weigh your baby unclothed on the same digital scale.

Primary Study Activities: Maximum 25 Days

- *During the study, you will complete the following schedule of foods/drinks:*
  - **Phase 1 (6 days):** Consume food and drinks you normally eat.
  - **Phase 2 (6 days):** Consume food and drinks only from the packouts provided. The foods in this packout contain either beef or plant-based beef, depending on which condition you were randomly assigned first. You will not be told which condition it is.
  - **Phase 3 (6 days):** Consume food and drinks you normally eat.
  - **Phase 4 (6 days):** Consume food and drinks only from the packouts provided. The foods in this packout contain either beef or plant-based beef, depending on which condition you were randomly assigned second. You will not be told which condition it is.
  - **Phase 5 (1 day):** Return to DPRI within 1 week of completing intervention diet B to return final collected breastmilk sample and complete a palatability taste test of ground beef and plant-based "ground beef."

- *During this time, you will complete the following at home:*
  - **Food/Drink Tracking (Phase 1 and 3):** You will be asked to complete 3, 24-hour dietary recalls (2 weekday, 1 weekend) where you report the foods you ate in the last 24 hours. We will assist you with all of these diet recalls over the phone and schedule them at times that work best for you.
  - **Food/Drink Tracking (Phase 2 and 4):** You will be asked to report your food and beverage intake with a menu checkoff and photos with information about the time and amount you consume.
  - **Breastmilk Samples**: You will use the manual breast pump provided to collect three 5 ml breastmilk samples per day post-feed, label sample bag with provided sticker, and write in the date and time in spaces on bag. Please store these in your freezer until they are returned to the study team.
  - **Breastmilk Log:** You will record start and stop time of each breastfeeding session throughout the study in a log.
  - **Questionnaires:** You will complete questionnaires throughout the study that ask about your feelings of hunger, appetite, food cravings, fullness, energy, and stress.
  - **Continuous Glucose Monitoring:** You will wear a continuous glucose monitor for the duration of the study. This will be replaced once at the end of phase 3 when you come for a study visit. You will not be able to see your glucose readings.

Study Visits at DPRI (5): Approx. 1 hour each.

- You will return to DPRI five times throughout the study. The first 4 visits will occur on the last day of each phase. The final visit will occur within one week of completing phase 4.
- *During the first return visit, you will*
  - Deliver breastmilk samples and logs that you have collected
  - Complete questionnaires related to your physical activity, digestive symptoms, and your baby's eating behavior

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  - Collect meal packouts
- *During visits 2 and 4, you will*
  - Deliver breastmilk samples and logs that you have collected
  - Deliver menu checkoff sheets and completed questionnaires
  - Complete questionnaires related to your physical activity, digestive symptoms, and your baby's eating behavior in person
  - Have your weight taken
  - Complete a weighed feeding with your baby. We will weigh your infant unclothed on a digital scale. You will then breastfeed your baby until your baby is finished, We will give you privacy for this. Once your baby finishes the feeding, we will again weigh your baby unclothed on the same digital scale.
  - Provide a breastmilk sample to the research team at the study visit
  - Replace your CGM (visit 2) one time (it will not last the duration of the study)
  - Collect meal packouts
- *At visit 3, you will*
  - Deliver breastmilk samples and logs that you have collected
  - Collect meal packouts
- *At the final visit ("Study Wrap up"), you will …*
  - Deliver final breastmilk samples and logs that you have collected
  - Complete a blinded "taste test" of the ground beef and plant-based "ground beef" and answer questions about your preferences.

How long will you be in this study and how many people will be in the study?

Participation in this study will last 25 days. There will be a total of 20 women enrolled in the study with their infants.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. They are described below:

Occasional (Between a 1-10% chance that this will happen)

a) **Continuous Glucose Monitor:** There is a small risk of infection, bruising, soreness, o nausea associated with the CGM. To minimize risk, CGM is inserted and set up with the support of qualified staff using sterile techniques. There is a risk of developing a small rash or rash-like symptoms including redness, bums, soreness, and itching from the tape used to secure the CGM to the skin during the study. This irritation generally clears up within 2 hours after removing the adhesive. It is important to make sure to clean the surrounding area after the glucose monitor is removed

b) **Breast Pump**: There is a small risk that you will experience soreness and mild nipple discomfort from collecting breastmilk samples (5 ml per sample) with a breast pump.

Rare (Less than 1% chance that this will happen)

a) **Questionnaires**: You will be asked to provide sensitive information about your health, mood, stress, and home environment. For some people, these questions can be uncomfortable to answer.

Change in Eating Habits: If you are not accustomed to eating beef or plant-based beef, your stomach and/or bowels may become slightly upset due to the changes in your usual food intake. While unlikely, breastfeeding infants could also experience temporary stomach upset due to maternal dietary changes. Any discomfort should stop within 1-2 days.
The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

No direct benefits to participants.

What will happen to the samples and/or data we collect from you?

As part of this study, we will collect data from 1) the surveys you complete and 2) relevant medical data extracted from the electronic health record. Dietary recall data will be recorded without your name in a database at the National Institutes of Health. This study will also collect data concerning your food intake along with data from the CGMs that you will wear. This study will also collect breastmilk samples. All data will be de-identified and stored for up to 3 years. Breastmilk samples may be stored for up to 10 years. Breast milk samples will be analyzed for fatty acid composition and other molecules. Future analyses could look at hormones, inflammatory or anti-inflammatory molecules, or similar biomarkers in your breast milk samples. None of your data or breastmilk samples will be sold for profit. This information will be protected as described below.

How will we protect your information?

We will take every step to protect your privacy and confidentiality. To protect your information:

- We will collect data using encrypted methods
- We will store data in secure servers maintained by Dell Medical School.

Information about you may be given to the following organizations:

- Representatives of UT Austin and the UT Austin Institutional Review Board.

We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you.

A description of this study 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.

Under certain situations, we may break confidentiality. If during the study we learn about child abuse or neglect, we will report this information to the appropriate authorities including the police and/or the Texas Department of Family and Protective Services.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for answering research questions related to maternal and infant nutrition. Your name and other information that can directly identify you will be deleted from the research data collected as part of the project as soon as practical after study data are collected.

What if we learn something about your health that you did not know?

As part of this study, we may learn medically relevant information about you. If we learn something that you may not know, we will contact you and provide information so you can decide if and how to inform your health care provider. Please note that although you will be wearing a CGM during this study, we will not be actively monitoring your glucose status. You understand that we are not undertaking any obligation to monitor your CGM data for abnormalities or concerns and are not assuming any responsibility to identify abnormalities or concerns. CGM data is being collected for research purposes only and any results related to this are not clinical.

How will we compensate you for being part of the study?

You will receive payment for participation in this study. Payments will occur upon completion of each stage of the study with adherence to the entire protocol as set forth below. If you do not complete the study, you will not receive payment for the parts not completed. You will be responsible for any taxes assessed on the compensation.

You will receive $50 for your participation in the first 3 days of the study and an additional $100 per week for the remainder of the study for a total of $350 for your completion of this study. If you withdraw from the research before the end of the study, you will not receive any payment for the portions of the study that you did not complete.

You will receive payment for visits, and other gifts including a breastpump. Payments will occur with cash or a prepaid card through Tango. You will be responsible for any taxes assessed on the compensation. Partial payment will occur as components are completed. No payment will occur for any time period that is not completed. The disbursements will be prorated over time:

- Complete Phase 1: $50
- Complete Phase 2: $100
- Complete Phase 3: $100
- Complete Phase 4 and Study Wrap Up: $100

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin. You are not waiving any of your legal rights by participating in this study.

What are the costs to you to be part of the study?

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There are no costs to you for participating in this study outside of traveling to/from DPRI clinic 4 more times during the study and refrigeration of food and breastmilk samples.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin, your doctor, or healthcare provider, etc. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, all data obtained prior to withdrawal will be retained.

Is it possible that you will be asked to leave the study?

You may be asked to leave the study if it is determined by your doctor or the research team that it is unsafe for you to continue. If any of the following issues come up, we will have to ask you to stop participating if you are unable or unwilling to:

- Eat only the food provided,
- Keep a record of the foods/beverages you consume using a menu checkoff, taking photos of food, and/or completing dietary records or recalls,
- Collect, freeze, and deliver breastmilk samples,
- Wear a CGM, or
- Follow all study procedures.

Contact Information for the Study Team

If you have any questions about this research, you may contact:
Marissa Burgermaster, PhD
Principal Investigator
Phone: 512-495-4715
Email: marissa.burgermaster@austin.utexas.edu

Or

Madalyn Rosenthal
Research Program Coordinator
Phone: 512-475-1692
Email: madalyn.rosenthal@austin.utexas.edu or super@austin.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board

The University of Texas at Austin

Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date