COVER PAGE

Comparison of Breast Pump Suction Patterns in Achievement of Coming to Volume in Breast Pump-Dependent Mothers of Critically Ill Infants
ICF

NCT# 06061913

July 28th, 2023

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and
AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study (this "Research Study")?

Comparison of Breast Pump Suction Patterns in Achievement of Coming to Volume in Breast Pump-Dependent Mothers of Critically Ill Infants.

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Leslie Parker PhD, 352-215-9360

4. Who is paying for this Research Study?

The study is funded by Medela Inc.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research? How long will you be involved?

The purpose of this of this study is to compare the effectiveness of three different breast pump suction patterns (suction rate, intensity and rhythm) on lactation outcomes among mothers of critically ill infants

who are using a breast pump to obtain milk for their infant and who at 6-8 days after birth, are at risk for not producing enough breast milk to feed their infants. Different breast pump patterns may increase the volume of breast milk mothers are able to obtain when pumping and may be more comfortable than the current suction pattern used in breast pumps. You will be involved in the study for 15 days but information about your infant's health will be collected until they are discharged and how long you continue providing breast milk to your infant will be collected for 6 months.

b) What is involved with your participation, and what are the procedures to be followed in the research?

After enrollment in the study, you will be provided education on optimizing breast pumping by a Research Nurse Coordinator, who is also an International Certified Lactation Consultant (IBCLC). You will be asked to complete an interview, questionnaire, and survey. You will be loaned a Medela Symphony (Plus) breast pump. Three drops of your breast milk will be collected daily for 15 days and used to measure the amount of sodium and potassium (electrolytes) which indicates whether your milk has "come in". If the sodium level is greater than 20 mM at day 6-8 indicating your milk has not "come in", you will be withdrawn from the study and referred to the hospital Lactation team for further support. At day 6-8, you will again have your pumping optimized and complete a short survey. If unable to visit during days 6-8, the research team will coordinate and provide transportation. If you are pumping more than 350 mLs (~12 ounces) per day, you will continue to use the breast pump you have been provided. If you are pumping 350 mL or less, you will be randomly (like a flip of a coin) to use one of 3 breast pump suction patterns. If randomized, you will complete a 5-minute survey, during the second week of the study, while using this selected pattern. You will return the Medela Symphony (Plus) and be loaned a different Medela Symphony pump (SMART pump) that will be programmed with the designated breast pump suction pattern. The SMART pump will also be available at your infant's bedside. You will use the SMART pump for the next 7 days. At day 15, you will be asked to complete two surveys. If your baby breastfeeds, the amount of breast milk they consumed will be measured, by weighing your baby before and after you breastfeed. How long you continue providing breast milk will be assessed once a month, for 6 months.

c) What are the likely risks or discomforts to you?

It may be possible that using a new breast pump suction pattern may not be as comfortable or as effective as the standard breast pump suction pattern. If this is the case, you should contact the study PI listed on Question #3. A study lactation consultant will contact you to discuss ways improve the comfort and effectiveness of breast pumping. We do not expect any harm or discomfort to you more than what you would experience during normal pumping. If you choose to withdraw from the study, you will be asked to return the SMART pump.

You and your baby's health information will be kept in a locked office and locked cabinet. Data is de-identified, when possible, but there is a possible risk of loss of confidentiality. The study may have other unknown risks at this time.

d) What are the likely benefits to you or to others from the research?

You will have use of a Medela Symphony (Plus) or SMART Pump for home use. Use of a new breast pump suction pattern may increase the amount of breast milk you pump.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

If you choose not to participate in the study, a breast pump will not be provided for home use. Hospital standard lactation support services are available as well as the normal standard care of care from your doctors and nurses.

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.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

You will pump your breasts, collect your milk, and bring it to the Neonatal Intensive Care Unit according to the instructions given to you by your infant's nurse.

7. What will be done only because you are in this Research Study?

a. After enrollment, a Research Nurse Coordinator, who is also an International Certified Lactation Consultant (IBCLC) and a member of the research team, will meet you at your baby's bedside or your hospital room. You will be provided education and printed information on how to make your breast pumping most effective while using the Medela Symphony (Plus), which is the same breast pump available in your hospital room and the NICU. You will be asked to complete a short 2-minute maternal interview about you and your health, a 3- minute lactation experience questionnaire, and a 3-minute mood survey.
b. Following the lactation consult, you will be loaned a Medela Symphony (Plus) breast pump to take home and use for 15 days or until your infant is discharged, whichever comes first.
c. As per standard practice in this NICU, you will be asked to bring all pumped breast milk to the NICU where it will be weighed, stored and used to feed your baby. We will collect information regarding how much breast milk you pump daily. Three drops (0.3 mL) of your breast milk will be collected daily [only if you are pumping at least 5mls (1 teaspoon) of milk] for 15 days and used to measure the amount of sodium and potassium (electrolytes) which indicates if your milk has "come in". The sample will be discarded after it is analyzed. If your baby breastfeeds during the study, the amount of breast milk she or he consumed will be measured by weighing your baby before and after you breastfeed.
d. At day 6-8, if your breastmilk sodium level indicates your milk has not "come in", you will be withdrawn from the study, no further data will be collected. You will be referred to the UF Shands Lactation Team for further support.
e. At day 6-8, all mothers will have a second visit with a lactation consultant and receive advice and printed information on how to make their breast pumping most effective. You will complete a short 3-minute survey, about your perceptions using the Medela Symphony Plus pump. If you are unable to visit your infant during days 6-8, the research team will coordinate and provide you transportation using Uber Health.

f. At day 6-8, if you are pumping more than 350 mLs (~12 ounces) per day, you will continue to use the breast pump you have been provided.
g. If at day 6-8, you are pumping 350 mL or less, you will be randomized (like a flip of a coin) to use one of 3 breast pump suction patterns. You will use one of two new breast pump suction patterns or the standard breast pump suction pattern you've been using. You will return the Medela Symphony (Plus) and be given a different Medela Symphony (SMART pump) that will be programmed with the designated breast pump suction pattern you've been randomized to use. The SMART pump has enhanced computer technology to record the pumping pressure you use, how long you pump, how often you pump and the amount of milk you pumped. A SMART pump will also be available for you to use, at your infant's bedside. You will be given a key tag, with your assigned ID number, to use when using the SMART pump so that your pumping information is recorded. This pump does not track your personal information. You will use the SMART pump for the next 7 days.
h. At day 9-11 and were randomized into a pumping pattern, you will also be asked to complete a 5-minute survey regarding your perceptions of the breast pump suction pattern you are using in week 2 of study.
i. At day 15, you will be asked to complete 2-3-minute survey regarding your lactation experience, and a 3-minute survey regarding your mood.
j. All breast pumps should be returned at the end of the study or when your infant is discharged, whichever comes first.
k. Mothers who haven't brought milk in 3 days, may be contacted at their infant's bedside, or via phone or text to remind them to bring all pumped milk to the NICU at their next visit.
l. How long you continue providing breast milk to their infants will be assessed monthly for 6 months or until you have stopped pumping and/or breastfeeding. If your infant is still hospitalized, this information will be obtained from your infant's medical record. If your infant has been discharged home, you will be sent a monthly survey via text message. You will be asked if you are still pumping and/or breastfeeding and how many feedings per day of breast milk your infant is feeding. If no response within 7 days, one reminder text will be sent to reply to survey.

If any identifiable information were collected as part of this research, it is possible that your research information with all personally identifiable information removed, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. All breast samples will be discarded after the electrolyte values collected.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect the following information: Medical record numbers for both mother and infant(s), infant's date of birth and discharge. Medical record numbers and mother's phone number will be stored on a UF secured computer. Phone numbers will be used to send texts messages through the UF approved Qualtrics survey site and to contact mothers to arrange the second lactation consultation.

Infant's date and time of birth will used to calculate hours to when your milk comes in, the amount of milk you pump daily, and how much of your breast milk your infant consumes daily.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- government agencies which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state and local health departments, and
- the IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You will be in the study for 15 days, but your infant's health information and whether you continue providing breast milk to your infant will be assessed for up to 6 months or until you stop providing breast milk to your infant.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

Up to 274 mothers (and their infant(s) are expected to participate

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

It may be possible that using a new breast pump suction pattern may not be as comfortable or as effective as the standard breast pump suction pattern. If this is the case, you should contact the study Lactation Consultant to discuss ways to improve the comfort and effectiveness of breast pumping. We do not expect any harm or discomfort to be more than what you would experience during normal pumping. If you choose to withdraw from the study, you will be asked to return the SMART pump.

You and your baby's health information will be kept in a locked office and locked cabinet. Data is de-identified, when possible, but there is a possible risk of loss of confidentiality. This research study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

You will have use of a Medela Symphony (Plus) or SMART Pump for home use. Use of a new breast pump suction pattern may increase the amount of breast milk you pump.

13b. How could others possibly benefit from this Research Study?

The information gained from this study may benefit future mothers of infant(s) admitted to the NICU who use a breast pump to have an increased breast milk supply with an alternative breast pump suction pattern. Using a SMART pump may help moms keep track of their pumped milk and schedule.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

Study staff are partial paid from Medela AG. but the outcome of this study does not impact their position.

13d. Will you be allowed to see the research information collected about you for this Research Study?

None of the research information collected in this study is added to you or your infant's medical record.

14. What other choices do you have if you do not want to be in this study?

You will bring your breast milk to the NICU per normal care. You will obtain a breast pump, if needed, through other means available. Standard lactation support services are provided through UF Shands Lactation Team and can be reached by asking a staff member to contact them for you.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- If the researchers believe it is in your best interest
- If you fail to use the pumping pattern you are designated to use
- If you stop pumping and/or no bring milk to the NICU for your baby.
- If the medical team decides that your breast milk is not a safe feeding option for your baby.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

Text messaging rates from your carrier may apply.

17. Will you be paid for taking part in this Research Study?

Mothers will be provided a payment card for amount listed following completion of the listed study event(s).

1. All mothers enrolled: optimization pumping session with the study Research Nurse Coordinator IBCLC, completion of the first MAACL, maternal interview, and lactation experience questionnaire. ($25.00)
2. All mothers that achieve SA: Following completion of the second pumping optimization session with the study Research Nurse Coordinator IBCLC and maternal perception survey, part A ($25.00)
3. All mothers that do not reach SA, will be withdrawn from the study and not eligible for further compensation.
4. Following completion of the second MAACL, lactation experiences survey, maternal perception survey (if randomized) and return of all "loaned" breast pumps ($50.00)

Total Compensation: Moms withdrawn at Week 1 (did not reach SA) $25.00.
All other moms (reaching SA) will receive up to ($100)

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands Hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting and Authorizing Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____

Consent Signature of Parent/Legal Representative Date

_____ _____

Print: Name of Legal Representative Print: Relationship to Participant

_____

Print: Name of Subject: