Optimal Feeding Tube Dwell Time in VLBW Infants to Reduce Feeding Tube Contamination

NCT# 03728608

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IRB Approved

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

If you are a parent, as you read the information in this Consent Form, you should put yourself in your baby's place to decide whether or not to allow us to collect research information about your baby.

Name of person seeking your consent: _____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. 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.

GENERAL INFORMATION ABOUT THIS STUDY

1. **Name of Participant ("Study Subject")**

   _____

2. **What is the Title of this research study?**

   Optimal Feeding Tube Dwell Time in VLBW Infants to Reduce Feeding Tube Contamination

3. Who do you call if you have questions about this research study?

Principal Investigator: Leslie Parker (352) 215-9360

4. Who is paying for this research study?

National Institutes of Nursing Research, the National Eczema Association, and the Pediatric Dermatology Research Alliance (PEDRA)

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 research study is to determine if the amount of bacteria in a premature infant's feeding tube changes the longer the feeding tube is left in place. Your baby is being asked to be in this research study because your baby is premature and requires a feeding tube to feed. The duration of the study is 4 weeks. At one year of age, the study team will follow-up by chart check or phone call to ask parent if infant had a medical diagnosis of the skin condition, eczema.

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

If you decide to have your baby participate in this research study, your baby will be randomly assigned (like the flip of a coin) to either have their feeding tube replaced every 48 hours or every 7 days. Your infant's discarded feeding tube will be collected once a week for this study and tested for the amount of bacteria in the feeding tube. In the event your baby has a decompression tube in place, this tube will be collected once a week and tested for the amount of bacteria also. A small sample of gastric secretions will be obtained initially to test the acidity of the infant's stomach contents. In addition, less than 4/10th of a teaspoon of your infant's stomach contents will be collected once week from the newly placed feeding tube and sent to the lab to test pH and to test for bacteria and inflammation. A weekly sample of infant's saliva will be obtained using a tiny soft brush to swab the infant's mouth. Weekly, a moist cotton tip swab will be rubbed on infant's arm to test for any skin bacteria. Finally, a weekly stool sample will be taken from your infant's diaper to test for bacteria and inflammation. A brief (less than 2 minute) phone call maybe made when infant reaches 1 year of age to determine if your baby was ever diagnosed with eczema (atopic dermatitis). This can be determined from your infant's online chart but if not documented, someone from the study team will call you.

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

There may be mild discomfort because your infant might have their feeding tube replaced earlier than he/she would if not in the research study. Changing feedings tubes more often may decrease the bacteria present in the feeding tube and therefore infants who have their feeding tube changed at 7 days may have an increased risk of infection. Comfort measures are routinely utilized during feeding tube removal and insertion in this NICU. Perforation of the stomach is an extremely rare complication of placing a feeding tube. This NICU uses a technique to place feeding tubes which further decreases the risk of this occurring.

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

Babies who have their feeding tube changed more often may have less bacteria in their feeding tube, and less bacteria and inflammation in their stomach and intestines. Information from this study could be used to increase the understanding of how the length of time a feeding tubes remains in place could affect the number of bacteria present in the feeding tube which may improve the infant's health

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

If you decide to not have your baby participate in this study, your baby will still receive the UF Health & Shands Children's Hospital routine clinical care and your infant's discarded feeding tube will not be analyzed for bacteria

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if your baby did not participate in this research study)?

Your infant will have a feeding tube placed and removed for clinical reasons unrelated to research. The care your baby receives will be the same for any premature baby who weigh less than 1500 grams (about 3.3 pounds). Feeds will be given through a tube into their stomach and will be increased daily until full feedings are reached. Administration of a special type of nutrition through the veins called parenteral nutrition will be provided until they are taking enough feeding for good nutrition and growth. Medications will be used as necessary per normal clinical care. Risks include feeding intolerance, necrotizing enterocolitis (an intestinal infection that occurs in 7-10% of premature infants) and spontaneous intestinal perforation (when a premature infant develops a hole in their intestines which occurs in 5% of very premature infants).

All infants born prior to 30 weeks gestation are given mothers breast milk or if unavailable, donated pasteurized breast milk for feedings until infants reach 32 weeks gestation (2 months before they were due to be born).

7. What will be done only because your baby is in this research study?

If you decide to have your baby participate in this research study, your baby will be randomly assigned (like the flip of a coin) to either have their feeding tube replaced every 48 hours or every 7 days.

Your infant's discarded feeding tube will be collected once a week for this study and tested for the amount of bacteria in the feeding tube. If your baby has a decompression tube instead of a feeding tube, this will be collected instead. A small sample of gastric secretions will be obtained initially to test the acidity of the infant's stomach contents. In addition, less than $4/10^{th}$ of a teaspoon of your infant's stomach contents will be collected once week from the newly placed feeding tube and sent to the lab to test for bacteria and inflammation. Withdrawing stomach contents from the feeding tube is often performed on infants with a feeding tube to make sure the tube is in the infant's stomach. Oropharyngeal swabs will be collected weekly by gently inserting a tiny soft brush into the infant's mouth and rotating the brush to collect

infant's saliva. The infant skin flora will checked by rubbing a moist cotton tip applicator on the baby's forearm once a week. Finally, a weekly stool sample will be taken from your infant's diaper to test for bacteria and inflammation. Information from your infant's medical chart including your infants gestational age, age in days, birth weight, race, gender, how long the feeding tube was in place, if antibiotics were given to your baby and for how long, if your infant had an infection, or complication, whether you baby was delivered vaginally or by cesarean section and what type of feeding he/she receives. A follow-up will be done at infant's one year of age to determine if infant diagnosed with eczema. Information will be collected from chart or a brief phone call if not documented.

Infants will all receive mom's breast milk for the duration of the 4 weeks of the study. If the mother is unable or unwilling to provide breast milk, donated pasteurized breast milk will be provided for the infant for the duration of the 4 weeks of the study.

If your infant is receiving donor milk and is discharged before the end of the study, he/she will be transitioned to formula according to normal NICU care

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

Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens 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.

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

8. How long will you be in this research study?

Your baby will be in the research study for 4 weeks.

9. How many people are expected to take part in this research study?

Up to 151 newborns are expected to participate in this study.

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

10. What are the possible discomforts and risks from taking part in this research study?

There may be mild discomfort because your infant might have their feeding tube replaced earlier than he/she would if not in the research study. Comfort measures are

routinely utilized during feeding tube removal and insertion in this NICU. Comfort measures implemented may include (1) the use of a pacifier dipped in a sweet solution for infants with a sustained suck and greater than 28 weeks gestation, (2) 0.2 ml of a sweet solution placed on the gums for infants that are greater than 28 weeks but too ill or immature to have a sustained suck, (3) all infant will be swaddling and/or tucking and (4) use of a securement device or taping method approved by the NICU to minimize skin irritation. However, nurses often reinsert feeding tubes frequently and therefore it is not anticipated that your infant will experience increased discomfort. Perforation of the stomach is an extremely rare complication of placing a feeding tube. This NICU uses a technique to place feeding tubes which further decreases the risk of this occurring. Changing feedings tubes more often may decrease the bacteria present in the feeding tube and therefore infants who have their feeding tube changed at 7 days may have an increased risk of infection.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another 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.

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

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.

11a. What are the potential benefits to you for taking part in this research study?

Babies who have their feeding tube changed more often may have less bacteria in their feeding tube, and less bacteria and inflammation in their stomach and intestines.

11b. How could others possibly benefit from this study?

Information from this study could be used to increase the understanding of how the length of time a feeding tubes remains in place could affect the number of bacteria present in the feeding tube which may improve the infant's health.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

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

If you decide to not have your baby participate in this study, your baby will still receive the UF Health & Shands Children's Hospital routine clinical care and your infant's discarded feeding tube will not be analyzed for bacteria.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw your infant from the study, no new information will be collected for study purposes. However, the researchers would like to use information that was already collected unless you indicate otherwise in writing.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- Your baby requires abdominal surgery

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No. There will be no extra cost to you for participating in this Research Study.

15. Will you be paid for taking part in this study?

No, you will not be paid for your baby's participation in this study.

16. What if you are injured because of the study?

Please contact Leslie Parker, Ph.D. at (352) 215-9360 if your baby experiences an injury or you have questions about any discomforts that your baby might experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to let your baby participate in this study, the Principal Investigator will create, collect, and use private information about your baby's health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your baby's protected health information may be collected, used, and shared with others to determine if they can participate in the study, and then as part of their participation in the study. This information can be gathered from your baby's past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Your infant's name, medical record number, date and time of birth, birth weight and gestational age, race, gender, how long the feeding tube was in place, if antibiotics were given to your baby and for how long, if your infant had an infection or complication, whether you baby was delivered vaginally or by cesarean section and what and how he/she is fed and if bacteria grew in the feeding tube and if so what type, the type and amount of bacteria in your infants stomach and intestine and whether there was inflammation.

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you.

For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To see if there is a relationship between how long the feeding tube is in place and what type of bacteria are present in the feeding tube
- To evaluate the results of the research study.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- Other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies who 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 who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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 & Authorization

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 hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. 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 & Authorization Signature of Parent/Legal Representative

Date

Print: Name of Legal Representative

Print: Relationship to Participant:

Print: Name of Subject: