MoCHA

Moderately Preterm Infants with Caffeine At Home for Apnea (MoCHA) Trial

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Neonatal Research Network

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Appendix L
Informed Consent Statement for:

MoCHA

You are being asked to allow your baby to be in a research study which will look at the use of caffeine in the hospital and after discharge. Caffeine is a medicine commonly used to treat *apnea of prematurity*. Babies who were born between 29 and 33 weeks gestational age and have a history of *apnea* will be part of this study.

It is important for you to understand why we are doing this research and what it means for your baby to be a part of the study. You may discuss this information with relatives, friends and others who help you make important decisions. If you have any questions about this research, please ask us.

This study is sponsored by the *Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*, which is part of the National Institutes of Health (NIH), and is being done at XXXXX by XXXXX (name of site and PI).

Investigator

Location

Telephone

Protocol Title
Randomized Controlled Trial of Home Therapy with Caffeine Citrate in Moderate Preterm Infants with Apnea of Prematurity (MoCHA) (Cooperative Multicenter Neonatal Research Network)

What is Apnea of Prematurity?

Apnea of prematurity is a common problem in babies who are born before their due date. Apnea is when babies stop breathing for a short period of time. Apnea may also cause slowing of their heart rate (bradycardia). Babies usually stop having apnea around the time of their due date. However, for some babies, apnea may last past this time and may delay discharge. The doctors worry that if premature babies go home before they stop having apnea they are at greater risk for having an "apparent life-threatening event" (ALTE). An ALTE is an apnea event with slowing of the heart rate (bradycardia) that is serious and may need emergency room care. Sometimes babies will be admitted to the hospital if they have apnea and bradycardia after going home. However, most doctors wait before sending premature babies home until they have not had apnea and/or bradycardia events for 5-7 days.

Why is Caffeine Used?

Caffeine is used to treat apnea in premature babies in the newborn intensive care units (NICUs). However, studies have shown that some babies still may have apnea after getting caffeine.

Why is this study being done?

The purpose of this research study is to find out if using caffeine until discharge and after discharge at home will help us send babies home sooner.

There are two main purposes for this study:

1. To find out if using caffeine until discharge will allow babies to go home sooner.
2. To find out if using caffeine during the first month after discharge can prevent or decrease apnea.

How many babies will take part in this study?

There will be 1200 babies enrolled from approximately 15 centers across the United States. XX hospital plans to enroll about XX babies.

How long will my baby be a part of this study?

Your baby will begin the study close to the time of discharge from the hospital and will continue to be a part of it for the first 56 days following discharge.

What will happen if my baby joins this study?

Babies that go into this study will be randomly assigned (like the toss of a coin) to one of two groups. There is an equal chance of being in either group.

Caffeine Group	Receives caffeine medication.
Placebo Group	Receives solution without caffeine.

The study will begin when your baby is close to discharge and the doctors decide your baby no longer needs caffeine. At this time your baby will be randomly assigned to receive either caffeine or a placebo (solution without caffeine). This study medication (caffeine or placebo) will be given each day until discharge. You will then receive the same study medication to give your baby daily for the first 28 days after he/she goes home.

Neither you nor your baby's doctors or nurses will know which group your baby is in. While in the hospital, your baby's nurses will give the study medication once a day. The dose of the study medication will be based on your baby's weight.

On the day of discharge, you will be given 28 small vials (bottles) of the same study medication. The vials will be numbered 1-28, and one vial will be used each day. We will teach you how to fill a small syringe with the correct amount of study medication each day. We will teach you how to give your baby the study medication once a day by mouth for the first 28 days after your baby goes home. We will also teach you how to properly store the study medication.

At discharge, we will give you a diary to fill out during the time your baby is in the study at home. The diary will have a place each day for you to mark that you gave your baby the study medication. It will also have spaces to write down things such as forgetting to give the medication, any regular doctor visits, unexpected doctor or emergency room visits or

any hospital admissions. We need you to fill this out every day for the first 28 days.

The last part of the diary will be used for the second month after discharge. We will need you to write down your baby's regular doctor visits, unexpected doctor or emergency room visits or any hospital admissions during this time.

We will keep in touch with you after your baby is discharged from the hospital. We will call about three days after discharge, once a week for the first four weeks, and then at about six and eight weeks after discharge. We will ask about what you have written on the diary. There will be no extra clinic visits for this study.

Besides this study medication, your baby will have all the usual care given to premature babies while in the hospital.

As part of the study, we will collect information from your baby's medical chart. This may include birth weight, gestational age, sex, problems he/she had while in the hospital, medications received and test results while in the hospital.

If your baby is transferred to another participating hospital before going home, all parts of the study will continue if possible, including the medical chart review.

If your baby is transferred to another NON-participating hospital before going home, all parts of the study will discontinue.

We will also collect information about you (mother), such as age, your years of education, marital status, race/ethnicity, type of insurance and health issues during your pregnancy. We will ask for your address, phone numbers, and email address so we can contact you when your baby goes home from the hospital. We may contact you in the future for further long term follow up for this study.

What are the risks and possible discomforts from being in this research study?

Because of being born early, your baby has a greater risk of having poor developmental outcomes, disabilities, or even death. Some babies have apnea and are at higher risk for an apparent life-threatening event (ALTE). These risks are the same whether or not your baby is in this study.

There may be other risks related to being in this study.

Caffeine is a commonly used drug which has a few side effects. Possible side effects may include:

- Slow weight gain
- Irritability or jitteriness
- Seizures or convulsions
- Irregular heart rate
- Higher heart rate
- Higher blood pressure

These side effects occur in about 1 to 5 of every 100 babies taking caffeine. These side effects are temporary and usually go away after stopping the medication. Your baby has already been given caffeine in the hospital and has been watched for these side effects. There are no known side effects for the babies who get the placebo.

Your baby will be put into a study group by chance. One group may be less effective or have more side effects than the other study treatment or other available treatment.

Unknown Risks

There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Confidentiality

Another possible risk of being part of this study is loss of confidentiality or privacy.

What are the benefits of joining this study?

There may be benefit if the study shows that babies in the group that gets caffeine go home sooner and have less apnea after discharge. This may prevent unexpected visits to the doctor or to the emergency room for problems with apnea.

All babies enrolled in this study, whether they are in the group that gets caffeine or placebo, may benefit from the closer monitoring by the study staff. Study staff will be contacting you often to check on you and your baby.

One treatment may have better outcomes than the other treatment. It is possible that neither group will show any improvement.

It is also possible that your baby will not get any benefit from being in this study. However, information that we learn from this study may help us to better care for premature babies in the future.

What other choices do I have if I do not allow my baby to be in this study?

You have the choice to not allow your baby to be in this study. If you choose not to allow your baby to join, he/she will receive the usual care given in the hospital and after discharge. This care may include keeping your baby in the hospital until all apnea has stopped, discharge with an apnea monitor and/or treatment with caffeine after discharge.

Will my baby's medical information be kept private/confidential?

<insert standard institutional language about confidentiality. Following is a sample>

Information obtained about your baby for this study will be kept confidential to the extent allowed by law. However, research that identifies your baby may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- *<Insert your institution. Following is a sample>* UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- Research Triangle Institute (RTI), the data coordinating center for the study
- Food and Drug Administration (FDA)
- Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however your baby's identity will not be given out. A copy of the consent form will be placed in your baby's medical record at *<Insert your institution. Following is a sample>* UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your baby's care

within this health system. The EMR may indicate that your baby is on a clinical trial and provide the name and contact information for the principal investigator.

Results of research tests or procedures may be placed in your baby's medical record. All information within your medical record can be viewed by individuals authorized to access the record. Information relating to the study, including name, date of birth and social security number, may be shared with the billing offices of *<Insert your institution. Following is a sample>* UAB and UAB Health System affiliated entities, along with Children's of Alabama and its billing agents so costs for clinical services can be appropriately paid for by either the study account or by your insurance.

Information about your baby that we collect for this study will be kept in a locked filing cabinet in our clinical research office, and on password-protected computers. This office is protected by security staff 24 hours a day, 7 days a week. Information collected from your baby's chart for this study will be labeled with coded study identification (ID) number. The log book connecting the code number with your baby's identity will be kept locked in a filing cabinet in our clinical research office, available only to research staff working on the study.

Coded information will be sent to the NICHD Neonatal Research Network's Data Coordinating Center at Research Triangle Institute (RTI) in Research Triangle Park, North Carolina. Information from this research study will be kept by *<Local Research Institution>* and RTI International and may be shared for future research in accordance with the NIH Public Access Policy and NIH Data Sharing Policy. Information released under this policy will not identify your baby or his/her participation in this research study.

A description of this research study will be available on ClinicalTrials.gov, ID number NCT 03340727, as required by United States law. This website will not include information that can identify you or your baby. The website will include a summary of the results of this study. You can search this website at any time.

This research study has a Confidentiality Certificate that protects your child's privacy. If a legal matter happens, researchers may not use any information that might identify your child unless you give your okay. You may give information about your child or this study to anyone you wish. If an insurer or employer learns that your child is in a study and you agree to share study data with them, the researcher will do so. This means that you must also guard your child's private information. The researcher may give information to authorities to prevent serious harm to you, your child, or others.

What are the costs of taking part in this research study?

You will not be billed, nor will your insurance company be billed, for any test, treatment or visit that is done only for this study. The parts of your baby's care that would normally be done as usual treatment, including (but not limited to) treatment with a mechanical ventilator, antibiotics, feeding by vein, or blood pressure medications, will be billed to you or your insurance company as usual. The study will pay for all parts of your baby's care that are done only for the study.

Will I be paid for taking part in this research study?

You will not be paid for your baby taking part in this study while your baby is in the hospital. However, after the diary is completed, and the

phone calls with study staff are done, you will receive a $30 gift card in the mail.

What happens if my baby is injured as a result of taking part in this research study?

In the event of physical injury to your baby resulting from their participation in this research, necessary medical treatment will be provided to your baby and billed as part of their medical expenses. Costs not covered by their insurance will be your responsibility. Also, it is your responsibility to determine the extent of your baby's health care coverage.

There is no program in place for other payment for such injuries. However, you and your baby are not giving up any legal rights or benefits to which you are otherwise owed.

Is participation in this study voluntary?

Yes, whether or not you allow your baby to be in this study is your choice. There will be no penalty if you decide not to allow your baby to be in the study. If you decide not to allow your baby to be in the study, your baby will not lose any benefits otherwise owed. You are free to withdraw your baby from the study at any time. Refusing to let your baby be in this study or deciding to take them out of it will not affect your relationship with this institution.

New Information

You will be told by the study doctor or study staff if new information is learned that might affect your choice to allow your baby to stay in the study. If you decide to take your baby out of the study at that time, the research doctor will make arrangements for your baby's medical care to continue as usual. If you decide to allow your baby to stay in the study, you will be asked to sign a new consent form.

Right of Investigator to Withdraw Participants

Your baby may be removed from the study without your permission if the sponsor ends the study or if the study doctor decides it is not in the best interest of your baby's health. Some reasons for taking your baby out include risks of being in the study are more than the benefits or if your baby develops a severe problem.

If I have questions or concerns about this research, whom can I contact?

If you have any questions, complaints, or concerns about the study you can contact the investigator (Dr. ___), the co-investigators (Drs. ___ or ___) or their staff by calling the University Paging Operator: (xxx) xxx-xxxx, the University NICU (xxx-xxx-xxxx or the ____ NICU (xxx) xxx-xxxx 24 hours a day. If you think your baby may have been harmed from being in this study, you can contact the same people.

Institutional Review Board

Contact the Institutional Review Board (IRB) if you have questions about your baby's rights when he/she takes part in research. Also, contact the IRB if you have questions, complaints or concerns that you do not feel you can talk about with the investigator. The University IRB may be reached by phone at (xxx) xxx-xxxx or by e-mail at irb@xxxxx.edu.

We are always available to answer your questions. If you have any questions that come up during this study, please be sure to ask us

STATEMENT OF CONSENT

I have read this Informed Consent document and have had the opportunity to ask questions. I will be given a signed copy of this form to keep.

I, as the parent or guardian, agree to let my baby to take part in this research study and allow you to use and collect and share health information about my baby for this study, as you have explained in this form.

_____
Baby's Name

_____
Parent/Guardian's Name

_____ _____
Parent/Guardian's Signature Date

_____
Relationship to Baby for Parent/Guardian

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date