The University of New Mexico Health Sciences Center
Consent to Participate in Research

Morphine versus Methadone for Infants with In-Utero Opiate Exposure and Neonatal Withdrawal Syndrome: A Pilot Study

4/9/2018

Introduction

You are being asked to participate in a research study that is being done by Dr. Nicole Yonke and a team of doctors from the Milagro Clinic in the Department of Family Medicine. This research is studying newborn infants exposed to opiates other than buprenorphine during pregnancy.

Infants exposed to opiates during pregnancy sometimes develop withdrawal symptoms, called Neonatal Abstinence Syndrome (NAS). At the University of New Mexico Hospital, infants who are exposed to methadone or heroin who need medication for NAS are treated on a weaning protocol with methadone. Infants exposed to buprenorphine are treated on a weaning protocol with morphine.

You are being asked to participate in this study because your child was exposed to opiates other than buprenorphine during your pregnancy.

This form will explain the research study, and will also explain the possible risks as well as the possible benefits to you. We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

What will happen if I decide to participate?

If you agree to participate, the following things will happen:

If your infant requires medication for neonatal abstinence syndrome (NAS) your infant will be assigned by chance (like a flip of a coin) to receive methadone or morphine to treat withdrawal. Your infant will have an equal chance of receiving either medicine. Your doctors will assess your baby multiple times per day and adjust the medication as necessary to treat withdrawal. When your baby is ready to be discharged from the hospital you will be asked to complete a questionnaire that asks about your experience in the hospital. You may refuse to answer any questions at any time. This questionnaire will take about 30 minutes to complete.

How long will I be in this study?

Participation in this study will last until your baby is discharged from the hospital.

What are the risks or side effects of being in this study?

We know that morphine and methadone are both safe and effective treatments for withdrawal. There is a chance that there are differences between the treatments that we do not yet know.

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

For more information about risks and side effects, ask the investigator.

What are the benefits to being in this study?

There may or may not be benefit to you from participating in this study.

It is hoped that information from this study will help in the future treatment of babies with NAS.

What other choices do I have if I do not want to be in this study?

You do not have to participate in this study for your baby to receive treatment for NAS. If you choose not to participate in this study and your baby withdraws, he/she will receive the standard treatment with methadone.

How will my information be kept confidential?

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information contained in your study records is used by study staff and, in some cases it will be shared with the sponsor of the study. The University of New Mexico Health Sciences Center Human Research Review Committee (HRRC) that oversees human subject research, and the Food and Drug Administration and/or other entities may be permitted to access your records. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study. A copy of this consent form will be kept in your medical record.

Information collected as part of this study will be labeled with your initials and a study number; information (without your name) will be entered into a computer database. Dr. Sutter and her team will have access to your study information. Subject's research data and study records will be maintained until the youngest subject turns 22 years old. Medical information created by this study may become part of your baby's medical record.

Information that does not become part of your child's record will be stored in the study file.

To help us further protect the confidentiality of your data, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this certificate, the investigators cannot be forced (for example by court subpoena) to discuss research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative or other proceedings. Disclosure will be necessary, however, upon request of DHHS or other federal agencies for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does note prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your child's participation, and obtains your consent to receive information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy and the confidentiality of your data.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm of your child or others.

What are the costs of taking part in this study?

Your third party payer (i.e. insurance company) will be responsible for all costs related to your child's clinical treatment.

What will happen if I am injured or become sick because I took part in this study?

If your baby is injured or becomes sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost.

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the

Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?

You will be compensated $20 as a merchandise card for participation in this study.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Nicole Yonke and the Milagro team will be glad to answer them at (505) 463-8293

If you need to contact someone after business hours or on weekends, please call (505) 463-8293.

If you would like to speak with someone other than the research team, you may call the UNMHSC HRRC at (505) 272-1129.

Whom can I call with questions about my rights as a research participant?

If you have questions regarding your rights as a research participant, you may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, you may also access the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

CONSENT

You are making a decision whether to have your child participate in this study. Your signature below indicates that you read the information provided. By signing this consent form, you are not waiving any of your (your child's) legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to let my child participate in this study. A copy of this consent form will be provided to you.

_____	_____	_____
Name of Parent/Child's Legal Guardian	Signature of Parent/Child's Legal Guardian	Date

INVESTIGATOR SIGNATURE

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____
Name of Investigator/ Research Team Member (type or print)

_____	_____
(Signature of Investigator/ Research Team Member)	Date