Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT)

This study is ongoing, but not recruiting participants.

**Sponsor:**
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

**Collaborators:**
National Heart, Lung, and Blood Institute (NHLBI)
National Center for Research Resources (NCRR)

**Information provided by (Responsible Party):**
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

### Purpose

This study compared the use of continuous positive airway pressure initiated at birth with the early administration of surfactant administered through a tube in the windpipe within 1 hour of birth for premature infants born at 24 to 27 weeks gestation. In addition, these infants within 2 hours of birth, had a special pulse oximeter placed to continuously monitor their oxygen saturation in two different target ranges (85-89% or 91-95%). This study helped determine whether or not these two management strategies affect chronic lung disease and survival of premature infants.

### Condition
- Infant, Newborn
- Infant, Low Birth Weight
- Infant, Small for Gestational Age
- Infant, Premature
- Bronchopulmonary Dysplasia
- Retinopathy of Prematurity
- Continuous Positive Airway Pressure

### Intervention
- Procedure: Early surfactant
- Procedure: Continuous Positive Airway Pressure (CPAP)
- Procedure: Target oxygen saturation of 85-89%
- Procedure: Target oxygen saturation of 91-95%

### Phase
- Phase 3

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**Study Type:** Interventional

**Study Design:**
- Allocation: Randomized
- Endpoint Classification: Safety/Efficacy Study
- Intervention Model: Factorial Assignment
- Masking: Open Label
- Primary Purpose: Treatment

**Official Title:** Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) in Extremely Low Birth Weight Infants

**Resource Links provided by NLM:**
- MedlinePlus related topics: Birth Weight, Oxygen Therapy, Premature Babies, Retinal Disorders

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[http://clinicaltrials.gov/ct2/show/study/NCT00233324?term=SUPPORT+oxygen&rank=1]
Permission Form

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants.

Principal Investigator: Nirupama Laroia, MD

Introduction
This permission form describes a research study and what you may expect if you decide to have your child participate. You are encouraged to read this form carefully and to ask the person who presents it any further questions you may have before making your decision whether or not to have your child participate.

Your child is being asked to participate in this study because your child will likely be born at 24 weeks to 27 weeks and 6 days gestational age (time from your last menstrual period) and your child may have breathing problems due to premature birth.

This form describes the known possible risks and benefits and describes what other choices for care or services are available to your child if you do not wish to have your child be in the study. You are completely free to choose whether or not to have your child participate.

Background
Many premature babies have difficulty expanding their lungs at birth and establishing breathing. The usual treatment is to give them oxygen and inflate their lungs with a ventilation bag. If breathing is not effective, then a small tube is passed into the windpipe to assist the baby's breathing using a ventilator (breathing machine or respirator). This is effective and is used for the majority of very premature babies who need assistance with their breathing. However, use of a breathing tube and mechanical ventilation can result in problems (complications) to the baby.

There is new evidence that even very premature babies might be helped to breathe on their own, without the need for a ventilator, if the lungs are gently and continuously inflated beginning soon after birth. This technique is called Nasal Continuous Positive Airway Pressure or Nasal CPAP; it means that oxygen is provided at constant pressure to the airway through a tube in the nostrils. Nasal CPAP is a treatment that is regularly used in neonatal intensive care to assist the breathing of babies with minor respiratory difficulties. It is most commonly used to help babies after they have been weaned from (taken off) the ventilator. Nasal CPAP is not usually used to help babies breathe immediately following birth, but it is used in a few hospitals. Available information suggests that this method may be successful in helping some infants born very prematurely.
There is currently no solid information that enables us to decide which of these techniques is best for assisting a baby’s initial breathing.

In addition, premature babies sometimes develop an eye disease known as Retinopathy of Prematurity (ROP) which can result in loss of vision or even blindness. The level of oxygen in the baby’s blood may have an effect on whether the baby develops ROP. All babies that are born prematurely have the amount of oxygen in their blood monitored almost continuously for several weeks using a pulse oximeter. The pulse oximeter measures the amount of oxygen by shining a light through the hand or foot. The light sensor is attached with tape like a bandage. The levels of oxygen in the blood usually range from 85% to 95%. We do not know, however, if it is better to keep the baby’s oxygen level in the lower range (85% - 89%) or the higher range (91% - 95%) and what effect this may have on developing ROP or long term development.

**Purpose of the Study**

The purpose of this research study is to find out whether starting nasal CPAP (providing oxygen through a nasal tube) at birth is better, just the same as, or worse than using a ventilator and breathing tube for babies born very prematurely. The study will also compare low range (85%-89%) oxygen saturation levels with high range (91% - 95%) levels to determine if a lower oxygen saturation range results in decreased eye disease (ROP), and is safe.

**Duration of Participation**

Study participation will begin as soon as the infant is born. The baby will remain in the study for the duration of hospitalization. Your baby will be followed after discharge through telephone interviews with you when your baby is six and twelve months of age, and either by telephone or in person when your baby returns for a follow-up study visit at 18-22 months after the date your baby would have been born if full term.

**Description of Study Procedures**

If you agree to have your baby participate in this study, your baby will be randomly assigned (like flipping a coin) prior to delivery to receive, either:

1. Continuous positive airway pressure (CPAP) in the delivery room immediately after birth and continuing in the NICU or
2. Assisted ventilation using a tube in the windpipe (endotracheal tube) followed by surfactant administration. Surfactant is a liquid that helps babies with immature lungs breath easier by helping to keep their lungs from collapsing. Surfactant may also be given to infants in the first group if they show they need it in the NICU.

In addition to being randomly assigned to one of these two groups, your baby will also be randomly assigned to 1 of 2 levels of blood oxygen. This will be done using special oximeters (oxygen monitors). Within the range of oxygen that we normally keep babies in (85 to 95%), your baby will either be in the high end of normal or the low end of normal. The nurse taking care of your baby or his/her physician will not know to which blood oxygen group your baby has been assigned. Your child will remain on this device until he/she reaches 36 weeks after
age (e.g., 24 weeks gestation plus 12 weeks of age = 36 weeks adjusted age).

Your baby will receive all standard care provided to any baby in the Neonatal Intensive Care Unit. No additional tests or procedures will be done on your baby just for this study. We will collect medical information regarding your baby’s time in the hospital from your baby’s medical chart. This will include laboratory values, any additional treatments that your baby receives and his or her progress over time.

We will continue to stay in touch with you and your infant by telephone every six months over the next 18 – 22 months. At these times, we will ask questions about your child’s breathing (especially wheezing and coughing), medication use, and visits to the Doctor, Emergency Room or Hospital for treatment of breathing problems. We will also ask you several questions about your family and yourself. The telephone calls should take about 15 minutes of your time, less if your baby has had no breathing problems.

We will schedule the telephone calls at a time that is convenient for you. The telephone calls will occur when your infant is 6, 12, and 18 months after his/her expected delivery at full term delivery date.

The results of your baby’s questionnaire will be combined with other infants from around the country. However, your baby’s name will not be used.

We will ask you to bring your baby in for a clinic visit at 18 to 22 months. At the follow-up visit your baby will receive testing of his or her muscles, nerves and mental and motor skills. This clinic visit will take approximately 2-4 hours.

Optional part of the Study
Standard of care in our NICU includes doing head ultrasounds at 1 – 14 days of age, at approximately 6 weeks of age, and at other times as deemed necessary for your baby’s care. If you agree, we would perform an additional test, a magnetic resonance imaging study (MRI) when your infant is at 35 – 42 weeks PMA, with a corresponding head ultrasound if one has not been done as standard of care. The MRI is a more advanced scan and can detect subtle differences in the brain that may not be seen on the head ultrasound. Your baby may or may not require light sedation while this MRI is being done.

Number of Subjects
Approximately 1300 babies will be enrolled in this study at 16 different centers across the country. Of those, approximately 50 will be enrolled at Golisano Children’s Hospital at Strong.

Risks of participation
The procedures that are being used are standard (routine) treatments used in neonatal intensive care. Special attention will be given to prevent any damage to the mucosa (soft tissue) of the
nostrils (if your baby receives a tube in the nostril) and/or the windpipe (if your baby receives a tube in the windpipe). Premature babies receiving either CPAP or assisted ventilation are at risk for lung problems, including leakage of air outside the lungs and prolonged need for oxygen. It is not clear that one treatment has a lower risk of this than another. Early use of surfactant (like in the babies who will get assisted ventilation) protects premature babies from severe lung disease and death. Continuous use of CPAP also improves these same outcomes. It is not clear that one treatment has a lower risk of this than another. To the best of our understanding, there will be no more risks for the baby in this study than are possible for any ill premature baby needing intensive care.

The MRI does not use x-rays. If your baby needs to have sedation for the study, the risks include sleepiness, slow breathing, or cessation of breathing. The incidence of these complications is low and your infant will be carefully monitored.

It is possible that the procedures that your baby receives will be less effective or have more risks or complications of prematurity than the other treatment but this will not be known until the end of the study. The incidence of these complications will be carefully measured in this study. We will take every precaution to minimize potential complications.

**Benefits of Participation**
Your baby may or may not benefit from participation in this study.

**New Study Findings**
You will be informed of any new findings, which may affect your decision to continue your baby’s participation in this research study. If you would like to know about the results of the research, please let Dr. Nirupama Laroia know, so that results can be provided on request at the completion of the study.

**Alternatives**
You may choose not to permit your child to participate in this study. If you choose not to enter your baby in this study, your baby will receive standard care. In that case, your baby’s doctor will decide whether to administer nasal CPAP, oxygen or ventilation to your baby, and standard blood oxygen levels will be used.

**Costs**
You or your insurance company will be responsible for the cost of standard medical care that your baby receives. There will be no additional costs as a result of your baby’s participation in this study. The follow up evaluation is provided at no cost and you and your child’s physician will receive a full report.

**Circumstances for Dismissal from the Study**
You will be dismissed from the study if the study sponsor decides to stop or cancel the study.
Sponsor Support
The University of Rochester is receiving payment from the National Institute of Child Health and Human Development, a division of the National Institutes of Health, for conducting this research study.

Compensation for Injury
The University of Rochester will provide medical care for any emergency medical problem that your child may experience as a direct result from your child’s participation in this research. You will not have to pay for this emergency care, but the university may seek reimbursement for this care from your health insurance carrier. Decisions regarding care and compensation for any research related injury will be made on a case-by-case basis.

Confidentiality of Records and HIPAA Authorization
While we will make every effort to keep information we learn about your baby private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your baby’s name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about your baby that we either create or use as part of the research. This permission is called an Authorization. We will use your child’s research record, related information from your child’s medical records, results of laboratory and other diagnostic tests obtained during his/her initial hospitalization, as well as information obtained during the 18-24 month follow up visit.

We will use your child’s health information to conduct the study, to monitor your child’s health status and to determine outcomes related to the use of this therapy for treating respiratory disease. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify your baby with the following people: The Department of Health and Human Services, the University of Rochester, the National Institutes of Child Health and Human Development (NICHD) and organizations (like the Research Triangle Institute) used by the NICHD to manage studies.

If you decide to have your child take part, your Authorization for this study will not expire unless you cancel (revoke) it. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, your child will be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to
be used and given to others. For example, information gathered during your child’s initial hospitalization may need to be sent to the NICHD Neonatal Research Network and to the Research Triangle Institute.

As stated in the section on Voluntary Participation below, you can also refuse to sign this permission/Authorization and not have your baby be part of the study. You can also tell us you want to withdraw your baby from the study at any time without canceling the Authorization. By signing this permission form, you give us permission to use and/or share your baby’s health information.

**Contact Persons**
For more information concerning this research or if you believe that your child has suffered a research-related injury, please contact: Nirupama Laroia, MD (principal investigator) at (585) 275-2972.

If you have any questions about your rights as a research subject, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315, Telephone: (585) 276-0005; for long-distance, you may call toll-free, (877) 449-4441.

**Voluntary Participation**
Taking part in this study is voluntary. You are free not to participate or to withdraw at any time, for whatever reason. If you do decide to withdraw, we will keep confidential the information we have collected. If you choose not to have your child participate or you wish to withdraw your baby from the study, your baby will not risk loss of present or future care your baby would otherwise expect to receive.

**Optional MRI**

☐ I agree to have the MRI performed on my child.

☐ I do not agree to have the MRI performed on my child.
Signatures/Dates

I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I give permission for my child to participate in this study. I will receive a signed copy of this form for my records and future reference.

Study Subject (Print)

Parent/Guardian Signature    Print Name    Date

Person Obtaining Consent

I have read this form to the parent/guardian of this subject and/or the parent/guardian of this subject has read this form. An explanation of the research was given and questions from the subject’s family were solicited and answered to their satisfaction. In my judgment, the parent/guardian has demonstrated comprehension of the information. I will provide the parent/guardian with signed copy of this consent form.

Signature, person conducting Informed Consent    Print Name    Date