

CONSENT FORM

DELIVERY ROOM MANAGEMENT OF PREMATURE INFANTS AT HIGH RISK OF RESPIRATORY DISTRESS SYNDROME

PATIENT NAME: _____

You are being contacted about the study “Delivery Room Management of Premature Infants at High Risk of Respiratory Distress Syndrome” because you are at risk of delivering a premature baby. We are requesting your permission to enroll your baby in the study. The purpose of this study is to determine which of three different methods of treating your premature baby at birth in the delivery room will reduce the risk of lung injury and inflammation (chronic lung disease). The three methods are:

1. to place small prongs in the nose directly after birth with a modest amount of positive air/oxygen flow (nasal continuous positive airway pressure or NCPAP),
2. to place a breathing tube into the windpipe (intubation) directly after birth, give surfactant into the lungs, and then remove the breathing tube and place the infant on NCPAP, or
3. to place a breathing tube into the windpipe (intubation) directly after birth, give surfactant into the lungs, and then place the infant on a breathing machine (ventilator).

Participation is voluntary. Your decision whether or not to participate will have no effect on the quality of your baby’s medical care. Please ask questions if there is anything you do not understand.

Why Should We Study This?

I understand that my baby is at risk of being born prematurely. Infants who are born prematurely are at risk for a variety of complications including respiratory distress syndrome (RDS). Respiratory distress syndrome causes breathing difficulty in infants whose lungs are not fully developed. The lungs normally produce a substance called pulmonary surfactant that helps keep the air sacks in the lungs filled with air during breathing. Infants with respiratory distress syndrome do not produce adequate amounts of pulmonary surfactant and the air sacks in the lung tend to collapse. This makes it difficult for the infant to breathe. I understand that because my baby is at risk of being born more than 10 weeks early, my baby is at high risk of developing respiratory distress syndrome.

Drugs have been developed which can help to prevent or treat respiratory distress syndrome in premature babies. These drugs, known as surfactant, are given directly into the baby’s lungs through a breathing tube in the windpipe. Infants with respiratory distress syndrome who require extra oxygen and help with a breathing machine routinely get treated with surfactant. In addition, infants at high risk of respiratory distress syndrome routinely get surfactant treatment to prevent the development of severe respiratory distress syndrome. Infants who receive surfactant have less lung injury and lung rupture, and fewer babies who receive surfactant die of complications of respiratory distress syndrome.

Despite the success of surfactant therapy, many premature infants will develop lung injury and inflammation (chronic lung disease). Nasal Continuous Positive Airway Pressure (NCPAP) may be a less invasive and traumatic way to treat respiratory distress syndrome. Studies that have examined the use of NCPAP suggest that the use of NCPAP in the stabilization of the premature infants at delivery may reduce the chances of getting chronic lung disease.

It is unclear which of these methods will give your baby the best chances for survival without chronic lung disease. In a few small studies, infants who were treated with NCPAP required fewer days on oxygen, fewer

days on breathing machines (ventilator), and fewer infants developed chronic lung disease. Some investigators have studied an approach that combines both of these therapies. Doctors in Scandinavia tested an approach where they intubated infants early in the course of respiratory distress, gave surfactant, and then removed the breathing tube and placed the infants on NCPAP. Infants treated in this fashion had improved oxygenation six hours after randomization and a reduced need for a breathing machine (ventilator) before discharge.

Since it is uncertain which of these three treatments is better, a research study is being performed in the Neonatal Intensive Care Unit at **[name of institution]**. This is a multi-center study organized by the Vermont Oxford Network, a voluntary collaborative organization of Neonatal Intensive Care Units. This study is partly funded by a grant from Ross Laboratories, the manufacturer of a surfactant preparation.

Randomization and Study Treatment

I understand that I am being asked to give permission for my baby to participate in this study that will compare these three approaches to treatment of respiratory distress syndrome in the delivery room. If my baby participates in this study, the treatment that my baby receives will be based on a method of randomization. Randomization means that my baby's caregiver will open a sealed envelope which will instruct him or her whether my baby will have either: nasal CPAP prongs placed in the nose directly after delivery [**NCPAP group**]; a breathing tube placed down my baby's windpipe (intubation), treatment with surfactant, the breathing tube removed and then be placed on nasal CPAP prongs directly after delivery [**ISX group**]; or a breathing tube placed down my baby's windpipe (intubation), treatment with surfactant and then placed on a breathing machine (ventilator)[**PS group**]. The chances of receiving any one of these treatments are approximately equal.

Infants randomized to the **PS group** will have a breathing tube placed (intubated) shortly after birth, receive surfactant administration and then be stabilized on a breathing machine (ventilator). The infant will have the breathing tube removed when stable at least 6 hours after surfactant treatment. Infants randomized to the **ISX group** will have a breathing tube placed (intubated) shortly after birth and receive surfactant administration. The breathing tube will be removed as soon as the infant is stable and needs less than 60% oxygen, and then the infant will be placed on nasal CPAP. Infants randomized to the **NCPAP group** will receive nasal CPAP prongs with positive pressure placed directly after birth. Should infants in the **NCPAP group** develop significant clinical signs of respiratory distress, then the infant will be intubated and given surfactant.

All other aspects of nursery care will be the same for the three groups of infants. I understand that if I do not choose to have my baby participate in this study, that my baby may still be treated with surfactant preparations and the choice of when to treat my baby will be made by my baby's caregiver.

Risks and Benefits

In preliminary studies, some benefits have been noted in infants who receive surfactant treatment early in the delivery room. In these studies, infants who were thought to be at risk for respiratory distress syndrome were intubated and given surfactant preparations. These infants spent less time on breathing machines, had less lung injury (pneumothorax), and improved survival. However, this approach to treatment will lead to more infants requiring intubation and surfactant treatment. There may be side effects of surfactant treatment. During the immediate period in which the dose is given down the windpipe, some instability of the infant may be noted (decreased heart rate or decreased blood oxygen). In studies of surfactant treatment, a slight increase in bleeding from the lungs (pulmonary hemorrhage) has been noted (2 infants for every 100 infants treated). Because surfactant is derived from an animal source, there is also the theoretical risk of transmission of infection. This has not been observed in studies to date.

NCPAP has been used in infants since 1972. It helps to keep the lungs expanded. Use of NCPAP may lead to fewer infants needing a breathing machine (ventilator) and chronic lung disease. No difference in survival rate has been reported. The side effects associated with NCPAP may include skin breakdown around the nostrils, feeding difficulties due to air in the stomach, and the risk for lung rupture (pneumothorax).

All infants with prematurity and respiratory distress syndrome are at risk for a large variety of complications besides those already mentioned. These may include bleeding into the brain (intraventricular hemorrhage), heart failure from persistent blood flow through an open blood vessel (patent ductus arteriosus), visual problems or blindness (retinopathy of prematurity), injury to the intestine (necrotizing enterocolitis), and long-term lung injury (bronchopulmonary dysplasia or chronic lung disease). Surfactant treatment or NCPAP has not been proven to have any positive or negative effects on these significant complications.

Data Collection

After my baby is randomized to receive either method of treatment (**PS group, ISX group, NCPAP group**) an experienced caregiver will be in attendance to administer the chosen therapy. Data will be collected regarding how much oxygen, NCPAP, or ventilation my baby is requiring. **If my baby requires additional oxygen therapy prior to discharge from the Intensive Care Unit or 4 weeks before my due date (whichever comes first), an “Oxygen Saturation Test” will be performed. The staff will slowly lower the amount of additional oxygen my baby is being given to see if the additional oxygen is needed to maintain normal levels of oxygen in the blood. In addition,** data will also be collected on my baby’s nutritional needs and growth. No specific blood tests or other studies are required for participation in the study. The individuals at **[name of institution]** conducting the study will also ask permission to contact you after your baby has been discharged home to determine the health of your baby at 2 years of age.

Compensation

I understand that there will be no additional charges for my baby’s participation in this study.

Although the individuals conducting the study will treat my baby’s disease or complications of the study, I understand that the **[name of institution]** and those individuals conducting the study will not provide monetary compensation or free medical treatment for injury to my baby resulting from these research procedures. I understand that I may contact **[name and title of Institutional Review Board contact person, address, phone number]** for more information on the subject or on how to proceed should I believe that my baby has been physically injured as a result of these research procedures.

Patient Privacy

The collection and submission of all medical information from this study will be accomplished with strict adherence to professional standards of confidentiality. Vermont Oxford Network will not be receiving any data that could potentially be used to identify your baby. Your baby’s name, date of birth or other personal patient identifiers will not be given to Vermont Oxford Network. Your baby will be assigned a unique patient identifier number in order to maintain data recording. Only your baby’s hospital will know the patient name associated with the unique patient identifier. I understand that the results of the study may eventually be published and that information may be exchanged between medical investigators, but that patient confidentiality will be maintained.

Consent

I have been given an opportunity to discuss this study with the caregiver(s) conducting the study, and I understand that I may ask further questions and that I may withdraw my baby from the study at any time without prejudice.

I agree to have my baby participate in the study and understand that I will receive a signed copy of this form.

Parent/Guardian

Date

Witness

Date

Physician/Caregiver

Date

Principal Investigator:

**[Insert:
Name
Address
Phone number]**