

Trial of Late Surfactant to Prevent BPD: A Pilot Study in Ventilated Preterm Neonates Receiving Inhaled Nitric Oxide

IRB# 2007-074

Principal Investigator: David Durand, MD

Synopsis:

The purpose of the study is to find out if giving Nitric Oxide gas followed by doses of surfactant medicine, called Infasurf® Surfactant, will improve lung function, allowing a decrease in the amount of oxygen and mechanical ventilator settings during the 24 day study period. We also want to see if this will reduce the risk of developing a chronic lung disease called Bronchopulmonary Dysplasia (BPD) in infants that receive both surfactant medicine and inhaled Nitric Oxide (iNO) gas therapy.

Nitric oxide is a natural gas produced in the lung that opens the blood vessels going to the lungs. iNO therapy is approved by the Food and Drug Administration (FDA) only for term infants born with a condition called pulmonary hypertension, in which blood flow to the lung is restricted. In previous animal studies, iNO has also been shown to reduce the resistance against the flow of air in the airways, and to promote growth and development of new lung and blood vessels.

Premature infants may be born with reduced amounts of nitric oxide, and a previous study of iNO therapy in premature infants after the 7th day of life has shown a reduction in time on the mechanical ventilator, as well as decreased development of BPD. In that study, the iNO therapy was well tolerated without significant short term side effects, and preliminary data suggests that there is no long term bad effects on development, although this portion of the study is not yet complete. The FDA has given permission to the investigators for use of iNO for this study.

Surfactant is a natural compound made in our lungs, and is required for normal breathing and survival. Many premature infants are born with reduced amounts of surfactant and benefit from surfactant medicine given through the breathing tube immediately after delivery. Some premature infants continue to require the breathing tube and the mechanical ventilator beyond the first week of life. Continued need for the mechanical ventilator, and increased levels of oxygen increase the risk of BPD. Previous studies have shown that very premature infants who continue to need the breathing tube and the mechanical ventilator beyond the first week of life may develop problems with the amount or the function of their own natural surfactant. This may increase their risk of developing BPD.

Infasurf® is a surfactant medicine approved by the FDA for use with premature babies who either have, or are at risk for respiratory distress syndrome with a lack of surfactant, and is given through the breathing tube. Infasurf® is only approved by the FDA for routine use soon after birth. However, in this research study we are using Infasurf® beyond the first week of life, instead of immediately after birth. The FDA has given permission to the investigators for use of Infasurf® beyond the first week of life. Infasurf® will be given through the breathing tube at the standard dose of 3 mL per kilogram weight.