# Early results of therapy for preemies not sustained

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Inhaled nitric oxide (iNO), a therapy used in the treatment of premature newborns with respiratory failure that had shown promising results in short-term studies, does not significantly improve long-term outcomes, according to a national study led by critical care researchers at the University of Pittsburgh School of Medicine and Children's Hospital of Pittsburgh of UPMC.

Previous studies of inhaled nitric oxide in premature babies with respiratory failure suggested improvements in early outcomes, but this study of nearly 800 infants found no significant improvement in survival rates at 1 year of age and no change in longer term respiratory or neurological function.

"We were surprised by these findings, because previous studies had suggested short-term benefits of iNO in the treatment of respiratory failure," said first author R. Scott Watson, M.D., M.P.H., assistant professor of critical care medicine and pediatrics, University of Pittsburgh School of Medicine, and an intensivist in the Division of Critical Care Medicine at Children's Hospital and a researcher in the Clinical Research, Investigation & Systems Modeling of Acute Illness (CRISMA) Laboratory in the Department of Critical Care Medicine. "Further study will determine if a different dose, longer duration of therapy and/or use in a different subgroup of premature babies would be effective."

Results of the study are published in the November issue of *Pediatrics,*

the official journal of the American Academy of Pediatrics.

Researchers conducted long-term follow-up of premature newborns from 16 centers in the United States who were born at 34 weeks or earlier and weighed between 500 and 1,250 grams and were enrolled in a study testing whether iNO could prevent chronic lung disease. Babies received five parts per million of iNO or a placebo within the first two days of birth and continuing for 21 days (or until the patient was taken off a ventilator). Of the 590 babies with complete survival data, 77 percent survived to one year of age (79 percent of those receiving iNO and 75 percent of those receiving placebo).

At 1 year of age, less than 6 percent of study participants were still receiving supplemental oxygen, but most had continued neurologic impairment. Less than 38 percent of survivors were unimpaired and nearly 35 percent had severe neurologic impairment. In all, nearly 45 percent of patients from the study had died, were on oxygen, or had neurologic impairment, and there were no significant differences between those who had received iNO and those who had received placebo.

"This was an important study because iNO has been proven an effective therapy for the treatment of respiratory failure in late-term and term infants," Dr. Watson said. "However, it may not be effective for smaller babies born at 34 weeks or younger. In addition, the discrepancy between the short-term and longer-term findings suggests that the conventional way of studying treatment for clinically ill infants and children, by looking at outcomes that develop in the hospital, is not enough to understand whether the treatments really work. We need to routinely study longer-term outcomes that are important to how children grow and develop over time."

Source: University of Pittsburgh Schools of the Health Sciences (news :

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