Extremely preterm infants enrolled in RCTs do not experience worse outcomes

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In a group of more than 5,000 extremely preterm infants, important in-hospital outcomes were neither better nor worse in infants enrolled in randomized clinical trials (RCTs) compared with eligible but nonenrolled infants, findings that may provide reassurance regarding concerns about performing RCTs in this vulnerable population, according to a study in the June 16 issue of *JAMA*.

It has been unknown whether participation in a neonatal RCT is independently associated with differences in outcomes. Elizabeth E. Foglia, M.D., of the University of Pennsylvania, Philadelphia, and colleagues compared in-hospital outcomes between extremely premature infants enrolled in RCTs and those who were eligible but not enrolled in RCTs conducted by the National Institute of Child Health and Human Development Neonatal Research Network between January 1999 and December 2012.

Six RCTs met the inclusion criteria. Of 5,389 eligible infants, 3,795 were enrolled in at least 1 RCT and 1,594 were not enrolled in any RCT. The researchers found that the primary outcome (a composite of death; bronchopulmonary dysplasia [a chronic lung disorder in infants]; severe brain injury; or severe retinopathy of prematurity [a sight-threatening abnormality of the eye]) did not differ significantly between groups (68 percent in enrolled group vs 69 percent in eligible but not enrolled group).There were no differences in the secondary outcomes (individual components of the primary outcome, culture-proven late-onset sepsis, and necrotizing enterocolitis (severe inflammation due to decreased

blood flow that occurs in the intestines of premature infants) in the adjusted analysis. In addition, the primary outcome did not differ between groups when analyzed by individual trial.

"The present study did not find differences in mortality or neonatal morbidity between trial participants and nonparticipants. Similarly, meta-analyses of studies of adults and older children have demonstrated no significant differences in outcomes between trial participants and nonparticipants who were treated similarly outside trials," the authors write.

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