

Clinical trial strives to provide optimal care during high-risk pregnancies

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Researchers are conducting a clinical trial to help determine the best timing of delivery in preterm pregnancies complicated by poor fetal growth. Preliminary results from the trial, which are published early online in *Ultrasound in Obstetrics & Gynecology*, demonstrate better than expected health outcomes in this high-risk group of fetuses.

Doctors are faced with a dilemma when deciding about the timing of delivery of a baby who does not grow adequately as a fetus, a condition called [fetal growth](#) restriction. To deliver early potentially exposes the baby to risks associated with being born immature, but to deliver late risks allowing other serious problems to develop due to a lack of nourishment and oxygen in the womb.

Doctors usually decide on the timing of delivery for a small baby in a high-risk [pregnancy](#) based on what they feel might be best for the baby, but without a solid basis in scientific facts.

Researchers designed a study—called the Trial of Randomized Umbilical and Fetal Flow in Europe (TRUFFLE)—in an attempt to help determine the best timing of delivery in preterm pregnancies complicated by fetal growth restriction. The study compares three groups of patients. In one group, the timing of delivery was based on monitoring the baby's heart rate. In the other two groups, timing was based on changes in the Doppler [ultrasound](#) measurement of one of the baby's blood vessels. A standardized prenatal monitoring and delivery protocol was used for all women in the trial. Ultimately, the investigators

hope to determine which monitoring practice is best for safeguarding development by measuring babies' neurological health at age two years.

In the meantime, the researchers now report early results from TRUFFLE performed in 20 European centers. The analysis includes 503 women who were pregnant for less than 32 weeks and whose babies were smaller than would be expected. The results revealed better health outcomes for the babies compared with recent reports: deaths were uncommon (8%), and most of the babies (70%) survived without severe health problems. Women with hypertension were at increased risk of having babies who died before or after birth or who had health issues.

"Although the effects of the different fetal monitoring practices on long-term neurodevelopment are not yet known, these management protocols would help effect a reduction in perinatal mortality and short term morbidity in pregnancies complicated by severe, early-onset fetal growth restriction," said lead investigator Christoph Lees, MD of Queen Charlotte's & Chelsea Hospital, London. "This is the largest prospective study of outcomes in pregnancies complicated by severe, early-onset fetal growth restriction showing that, at least in part, a standardized antenatal management protocol was responsible for the improved neonatal outcomes," said co-author Basky Thilaganathan, MD, PhD, and Editor-in-Chief of *Ultrasound in Obstetrics & Gynecology*.

Dr. Lees noted that the two-year outcomes of the babies in the study will be available in 2014, which may provide clues about what management and monitoring strategy is best to optimize long term neurodevelopmental outcome.

More information: "Perinatal morbidity and mortality in early-onset fetal growth restriction: cohort outcomes of the trial of randomized umbilical and fetal flow in Europe (TRUFFLE)." C. Lees, N. Marlow, B. Arabin, C. M. Bilardo, C. Brezinka, J. B. Derks, J. Duvekot, T. Frusca,

A. Diemert, E. Ferrazzi, W. Ganzevoort, K. Hecher, P. Martinelli, E. Ostermayer, A. T. Papageorghiou, D. Schlembach, K. T. M. Schneider, B. Thilaganathan, T. Todros, A. Van Wassenaer-Leemhuis, A. Valcamonico, G. H. A. Visser, and H. Wolf, on behalf of the TRUFFLE Group. Ultrasound in *Obstetrics & Gynecology*; Published Online: September 23, 2013. [DOI: 10.1002/uog.13190](https://doi.org/10.1002/uog.13190)

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