2 year neurodevelopmental and intermediate perinatal outcomes in infants with very preterm fetal growth restriction (TRUFFLE): a randomised trial.

No consensus exists for the best way to monitor and when to trigger delivery in mothers of babies with fetal growth restriction. We aimed to assess whether changes in the fetal ductus venosus Doppler waveform (DV) could
be used as indications for delivery instead of cardiotocography short-term variation (STV). In this prospective, European multicentre, unblinded, randomised study, we included women with singleton fetuses at 26-32 weeks of gestation who had very preterm fetal growth restriction (ie, low abdominal circumference [95th percentile]). We randomly allocated women 1:1:1, with randomly sized blocks and stratified by participating centre and gestational age (=29 weeks), to three timing of delivery plans, which differed according to antenatal monitoring strategies: reduced cardiotocograph fetal heart rate STV (CTG STV), early DV changes (pulsatility index>95th percentile; DV p95), or late DV changes (A wave [the deflection within the venous waveform signifying atrial contraction] at or below baseline; DV no A). The primary outcome was survival without cerebral palsy or neurosensory impairment, or a Bayley III developmental score of less than 85, at 2 years of age. We assessed outcomes in surviving infants with known outcomes at 2 years. We did an intention to treat study for all participants for whom we had data. Safety outcomes were deaths in utero and neonatal deaths and were assessed in all randomly allocated women. This study is registered with ISRCTN, number 56204499.

Between Jan 1, 2005 and Oct 1, 2010, 503 of 542 eligible women were randomly allocated to monitoring groups (166 to CTG STV, 167 to DV p95, and 170 to DV no A). The median gestational age at delivery was 30·7 weeks (IQR 29·1-32·1) and mean birthweight was 1019 g (SD 322). The proportion of infants surviving without neuroimpairment did not differ between the CTG STV (111 [77%] of 144 infants with known outcome), DV p95 (119 [84%] of 142), and DV no A (133 [85%] of 157) groups (p_trend=0·09). 12 fetuses (2%) died in utero and 27 (6%) neonatal deaths occurred. Of survivors, more infants where women were randomly assigned to delivery according to late ductus changes (133 [95%] of 140, 95%, 95% CI 90-98) were free of neuroimpairment when compared with those randomly assigned to CTG (111 [85%] of 131, 95% CI 78-90; p=0.005), but this was accompanied by a non-significant increase in perinatal and infant mortality. Although the difference in the proportion of infants surviving without neuroimpairment was non-significant at the primary endpoint, timing of delivery based on the study protocol using late changes in the DV waveform might produce an improvement in developmental outcomes at 2 years of age. ZonMw, The Netherlands and Dr Hans Ludwig Geisenhofer Foundation, Germany.

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