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Planned Early Delivery or Expectant Management for Late Preterm Pre-eclampsia (PHOENIX): A Randomized Controlled Trial — Source link

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Topics: Randomized controlled trial

Planned early delivery or expectant management for late preterm pre-eclampsia: a randomised controlled trial (PHOENIX trial).

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Summary

Background

In women with late preterm pre-eclampsia between 34 and 37 weeks' gestation the optimal time to initiate delivery is unclear, as limitation of maternal disease progression needs to be balanced against complications for the infant related to ongoing expectant management or planned early delivery.

Methods

In this UK parallel-group, non-masked, multi-centre, randomised controlled trial, we compared planned delivery against expectant management (usual care) with individual randomisation in women with late preterm pre-eclampsia from 34 up to 37 weeks' gestation and a singleton or dichorionic diamniotic twin pregnancy. The co-primary maternal outcome was a composite of maternal morbidity with the addition of recorded systolic blood pressure ≥160 mmHg. The co-primary perinatal outcome was a composite of perinatal deaths or neonatal unit admission up to infant hospital discharge. Analyses were by intention to treat. The trial was prospectively registered with the ISRCTN Registry, number 01879376.

Findings

Between 29 September 2014 and 10 December 2018, 901 women were recruited across 46 maternity units. 450 women (448 women and 471 infants analysed) were allocated to planned delivery, and 451 women (451 women and 475 infants analysed) to expectant management. The incidence of the co-primary maternal outcome was significantly lower in the planned delivery group (64·7%) compared to the expectant management group (75·3%); adjusted risk ratio 0·86 (95% CI 0·79 to 0·94); p<0·01. The incidence of the co-primary perinatal outcome was significantly higher in the planned delivery group (41·8%) compared to the expectant management group (33·5%); adjusted risk ratio 1·26 (95% CI 1·08 to 1·47); p<0·01. There were nine serious adverse events in the planned delivery group and twelve in the expectant management group.

Interpretation

There is strong evidence to suggest that planned delivery reduces maternal morbidity and severe hypertension, with more neonatal unit admissions related to prematurity, but no indicators of greater neonatal morbidity, compared to expectant management.