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

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1 Planned early delivery or expectant management for late preterm pre-eclampsia: a randomised 2 controlled trial (PHOENIX trial). 3 ¹Lucy C Chappell PhD 4 ²Peter Brocklehurst FRCOG 5 ³Marcus Green 6 7 ⁴Rachael Hunter MSc 8 ²Pollyanna Hardy MSc ⁵Edmund Juszczak MSc 9 10 ⁵Louise Linsell DPhil ⁶Neil Marlow DM 11 12 ¹Jane Sandall PhD ¹Andrew Shennan MD 13 14 15 ¹ Department of Women and Children's Health, School of Life Course Sciences, King's College London, London, UK. 16 ² Birmingham Clinical Trials Unit, University of Birmingham, UK. 17 18 ³ Action on Pre-eclampsia, 80 High St, Evesham WR11 4EU. ⁴ Research Department of Primary care and Population Health, University College London, London 19 20 UK. ⁵ National Perinatal Epidemiology Unit Clinical Trials Unit, Nuffield Department of Population Health, 21 22 University of Oxford, Oxford UK ⁶ UCL EGA Institute for Women's Health, University College London, London UK. 23 24 25 Corresponding author: Professor Lucy Chappell, Department of Women and Children's Health, School of Life Course Sciences, King's College London, Westminster Bridge Road, London, SE1 7EH; 26

Summary

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

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

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- 46 Findings
- 47 Between 29 September 2014 and 10 December 2018, 901 women were recruited across 46
- 48 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
- 50 incidence of the co-primary maternal outcome was significantly lower in the planned delivery group
- 51 (64.7%) compared to the expectant management group (75.3%); adjusted risk ratio 0.86 (95% CI
- 52 0.79 to 0.94); p<0.01. The incidence of the co-primary perinatal outcome was significantly higher in
- 53 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.

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