Correction : Induction of labour versus expectant monitoring for gestational hypertension or mild pre-eclampsia between 34 and 37 weeks' gestation (HYPITAT-II)

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Correction: Induction of labour versus expectant monitoring for gestational hypertension or mild pre-eclampsia between 34 and 37 weeks' gestation (HYPITAT-II): a multicentre, open-label randomised controlled trial

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The earliest draft versions of the protocol for our study described the composite adverse maternal outcome as one or more of progression to severe disease, pulmonary edema, thrombo-embolic disease, HELLP syndrome, eclampsia, placental abruption or maternal death. However, there is ongoing debate as to whether progression to severe disease should be considered an adverse maternal outcome [1,2]. Therefore, after obtaining funding which enabled us to increase our sample size to the current sample size of 680, we decided to study a composite adverse maternal outcome excluding progression to severe disease. These changes were incorporated in the protocol as submitted to and approved by the institutional review board;* the current protocol is available from our website (http://www.studies-obsgyn.nl/hypitat2/page.asp?page_id=642). Unfortunately, the change to the maternal outcome definition was not incorporated into the published protocol, which incorrectly includes progression to severe disease in the composite adverse maternal outcome [3].

We also discovered minor differences between the published protocol and the IRB approved protocol. The definition for neonatal morbidity should have contained meconium aspiration syndrome, pneumothorax and/or pneumomediastinum, periventricular leucomalacia, convulsions and other neurological abnormalities. Finally, low 5-minute Apgar score should have been defined as below 7 (as opposed to below 3), and low umbilical artery pH as below 7.05 (as opposed to below 7.0).

These discrepancies were discovered and the correction submitted for publication during recruitment.

* Medical Ethics Committee, Academic Medical Centre, Amsterdam, the Netherlands (ref. 2008/244).

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