Erratum to: Pessaries in multiple pregnancy as a prevention of preterm birth

Liem, Sophie M. S.; Bekedam, Dick J.; Bloemenkamp, Kitty W. M.; Kwee, Anneke; Papatsonis, Dimitri N. M.; van der Post, Joris A. M.; Lim, Arianne C.; Scheepers, Hubertina C. J.; Willekes, Christine; Duvekot, Johannes J.

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Corrections: Pessaries in multiple pregnancy as a prevention of preterm birth: the ProTwin Trial

Sophie MS Liem1,5*, Dick J Bekedam1, Kitty WM Bloemenkamp2, Anneke Kwee3, Dimitri NM Papatsonis4, Joris AM van der Post5, Arianne C Lim3, Hubertina CJ Scheepers6, Christine Willekes7, Johannes J Duvekot7, Marc Spaanderman8, Martina Porath9, Jim van Eyck10, Monique C Haak11, Marielle G van Pampus12, Hein W Bruinse3, Ben Willem J Mol5 and Maud A Hegeman1

The initial sample size calculation in our protocol [1] was based on the expected proportion of ‘bad neonatal outcome’ in the intervention group (3.9%) and control group (7.2%) and accounts for the fact that the outcomes in children from multiple pregnancies are non-independent using an intra class correlation of 0.6. As the intervention is performed on the mother, analysis should be done on the maternal level. This adjustment was made during recruitment and approved by the medical ethics committee. The sample size is calculated based on the primary outcome ‘bad neonatal outcome’. In the control group, ‘bad neonatal outcome’ is expected in 7.2% of the children (1.8% * 77% + 5.4% * 35% + 7.2% * 12% + 35.6% * 8% + 50% * 5% = 7.2%). In this calculation, the first rate represents the probability that a patient delivers at that gestational age, whereas the second rate represents the probability of ‘bad neonatal outcome’ at that particular gestational age. In case of treatment, ‘bad neonatal outcome’ is then expected in 3.9% of the children (0.9% * 77% + 2.7% * 35%+ 3.6% * 12% + 17.8% * 8% + 75% * 5% = 3.9%).

On the mother level this corresponds to an expected ‘bad neonatal outcome’ in at least one of two children of 12.4% in the control group and 6.7% in case of treatment. Using a two-sided test with an alpha of 0.05 and a power of 0.80 we need 400 women in the control group and 400 in the intervention group.

* Medical Ethics Committee, Academic Medical Centre, Amsterdam, the Netherlands (ref. No. MEC 09/107).

Author details
1Department of Obstetrics and Gynaecology, Onze Lieve Vrouwe Gasthuis Amsterdam, Amsterdam, the Netherlands. 2Department of Obstetrics and Gynaecology, Academic Medical Centre Amsterdam, Amsterdam, the Netherlands. 3Department of Obstetrics and Gynaecology, UMC Maastricht, Maastricht, the Netherlands. 4Department of Obstetrics and Gynaecology, AMC hospital, Amsterdam, the Netherlands. 5Department of Obstetrics and Gynaecology, Academic Medical Centre Amsterdam, Amsterdam, the Netherlands. 6Department of Obstetrics and Gynaecology, Academic Hospital Maastricht, Maastricht, the Netherlands. 7Department of Obstetrics and Gynaecology, Erasmus Medical Center Rotterdam, Rotterdam, the Netherlands. 8Department of Obstetrics and Gynaecology, University Medical Center St Radboud Nijmegen, Nijmegen, the Netherlands. 9Department of Obstetrics and Gynaecology, Maxima Medical Center Veldhoven, Veldhoven, the Netherlands. 10Department of Obstetrics and Gynaecology, Isala Hospital, Zwolle, the Netherlands. 11Department of Obstetrics and Gynaecology, VU Medical Center Amsterdam, Amsterdam, the Netherlands. 12Department of Obstetrics and Gynaecology, University Medical Center Groningen, Groningen, the Netherlands.

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