Correction: Study protocol for a randomised trial for atosiban versus placebo in threatened preterm birth: the APOSTEL 8 study


The article has been corrected since it was published online. The authors would like to notify on the following changes done in the paper.

Under the heading Abstract.
Old text: A sample size of 1514 participants (757 per group) will detect a reduction in adverse neonatal outcome from 10% to 6% (alpha 0.05, beta 0.2).
New text: A sample size of 760 participants (380 per group) will detect a reduction in adverse neonatal outcome from 11.95% to 6% (alpha error 0.05, beta error 0.2).

Under the heading Monitoring and safety.
Old text: A formal interim analysis is planned after data collection of 500 and of 1000 women.
New text: A formal interim analysis is planned after data collection of 500 women.

Under the heading Sample size.
Old text: Based on the APOSTEL three data, the proportion of adverse perinatal outcome in women randomised between 30 and 34 weeks’ gestation and treated with atosiban was 6%.10 To show a 40% reduction (10% in the placebo group to 6% in the atosiban group), we need to randomise 1438 women (beta error 0.2; alpha error 0.05). Assuming a 5% drop-out or loss-to-follow-up rate, we will randomise 1514 women (757 in each arm).
New text: Based on the APOSTEL three data, the proportion of adverse perinatal outcome in women randomised between 30 and 34 weeks gestation and treated with atosiban was 6%. Based on two recent studies,27,28 we expect a 49.8% reduction of 11.95% adverse perinatal outcome in the placebo group to 6% in the atosiban group. Therefore, we need to randomise 722 women (beta error 0.2; alpha error 0.05). Assuming a 5% drop-out rate, we need to randomise 760 women (380 in each arm).

New references

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