Prevention of preterm birth using cervical pessary in pregnant women after threatened preterm labour

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Objective
Cervical pessary has already been described to be effective in the prevention of preterm delivery in asymptomatic women with short cervical length (PECEP Trial – NCT00706264). Thus, we propose the use of a cervical pessary for preventing preterm birth in singleton pregnant women having a short cervical length after an episode of threatened preterm labour (TPB). Principal: To evaluate whether placement of a vaginal pessary in singleton pregnancy with short cervical length (≤ 25 mm between 24.0 and 29.6 weeks and ≤ 15 mm between 30.0 to 33.6 weeks) after TPB leads to a reduction in the incidence of spontaneous delivery before 34 completed weeks compared with expectant management. Secondary: • To compare the rate of preterm delivery before 28, 32 and 37 weeks. • To quantify and compare the needs of admission at hospital and needs of tocolysis and other treatments during pregnancy between the two study groups. • To assess morbidity and mortality in newborns comparing the two study groups. • To evaluate the incidence of maternal adverse effects secondary to the pessary placement.

Methods
A randomised, open controlled trial (PECEP-RETARD Trial) (1:1) was undertaken to ascertain whether the insertion of a cervical pessary in singleton pregnant women having a short cervical length (CL) after an episode of threatened preterm labour reduces the rate of early preterm delivery. The PECEP-RETARD Trial was undertaken in Vall d’Hebron Hospital in Spain. 352 pregnant women with a short CL after an episode of TPB were randomly assigned to receive a cervical pessary or expectant management without a cervical pessary (1:1 ratio). 15 patients were lost to follow-up (9 in the expectant group and 6 in the pessary group). Because of the nature of the intervention, this study was not blinded. The primary outcome was spontaneous delivery before 34 weeks of gestation. Neonatal morbidity and mortality were also evaluated. All analyses were by intention to treat. This study is registered as ClinicalTrials.gov NCT01242384.

Results
No differences were observed in the rate of spontaneous preterm birth before 34 weeks of gestation. However, spontaneous delivery before 37 weeks of gestation was significantly less frequent in the pessary group than in the expectant management group (25% vs 14%); p 0.02. No differences were observed in neonatal morbidity or mortality. No serious adverse effects associated with the use of a cervical pessary were observed.

Conclusion
The insertion of a cervical pessary reduces the rate of spontaneous preterm delivery in women with a short cervix after an episode of threatened preterm labour. As far as we know this is the first trial showing that the pessary reduces the rate of late prematurity.