Cervical pessary to prevent preterm birth in twin's pregnant women with a short cervix: a multicentre randomised controlled trial (PECEP-Twins)

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Objective

To evaluate whether placement of a vaginal pessary in twin pregnancies with short cervical length (≤ 25 mm) measured at 23 weeks leads to a reduction in the incidence of spontaneous delivery before 34 completed weeks compared with expectant management. Secondary objectives: To quantify and compare the need of admission to hospital and need of tocolysis and other treatments during pregnancy between the two study groups. To assess morbidity and mortality in newborn twins comparing the two study groups. To evaluate the incidence of maternal adverse effects secondary to the pessary placement.

Methods

A multicentre, randomised, open controlled trial (PECEP-TWINS Trial) (1: 1) was undertaken to ascertain whether the insertion of a cervical pessary in twin's pregnant women with a short cervix identified by routine transvaginal scanning at 20-23 weeks' gestation reduces the rate of early preterm delivery. The PECEP-TWINS Trial was undertaken in 5 hospitals in Spain. Cervical length was measured in 2, 287 women; 137 pregnant women with a cervical length ≤ 25 mm (of 154 detected with a short cervix) were randomly assigned to receive a cervical pessary or expectant management without a cervical pessary (1: 1 ratio). Three patients were lost to follow-up. 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 NCT01242410.

Results

Spontaneous delivery before 34 weeks of gestation was significantly less frequent in the pessary group than in the expectant management group (11/68 (16. 2%) vs 17/66 (25. 7%); p 0. 0001. 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 early preterm delivery in women with a short cervix.