

## **Cervical pessary versus vaginal progesterone in women with a singleton pregnancy**

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### **Objective**

Women with a singleton pregnancy and a short cervix are at increased risk for preterm birth (PTB). Vaginal progesterone prevents PTB in these women, while cervical pessary might be effective too.

### **Methods**

We performed an open-label multi-centre randomized clinical trial in 20 hospitals in the Netherlands. Women with a singleton pregnancy, a midtrimester cervical length  $\leq 35$ mm and no history of spontaneous (s)PTB  $< 34$  weeks were eligible. Participants were randomized in a 1: 1 ratio to receive either an Arabinâ cervical pessary or vaginal progesterone. Primary outcome was a composite adverse perinatal outcome. Secondary outcomes were rates of (s)PTB before 28, 32, 34 and 37 weeks. Sample size was set at 628 women. Treatment effect was expressed as relative risk (RR) and 95% confidence intervals (CI). Analysis was by intention-to-treat (EUCTR2013-002884-24-NL).

### **Results**

From July 2014 to March 2022, we randomized 635 women (pessary N=315, progesterone N=320). The composite adverse perinatal outcome occurred in 6.3% in the pessary group versus 5.5% in the progesterone group (crude RR 1.1; 95% CI 0.60 - 2.2). The rates of (s)PTB before 28, 32, 34 and 37 weeks were not significantly different in both groups. In a subanalysis of women with a cervical length  $\leq 25$  mm, the composite neonatal outcome was significantly higher in the pessary group compared to the progesterone group (24.2% vs 11.6%, RR interaction 4.72, 1.16-19.2, p 0.031). Overall, differences were more favourable for progesterone in women with a cervical length  $\leq 25$ mm.

### **Conclusion**

No superiority of a pessary over progesterone was found in the prevention of a composite perinatal outcome. In the subgroup of women with a cervical length of  $\leq 25$  mm, a pessary was significantly less effective in preventing a composite adverse perinatal outcome than progesterone. In singletons with a midtrimester short cervix, vaginal progesterone is the preferred treatment.