

## English Summary

**Background:** Observational studies have found a higher incidence of neonatal adverse respiratory and composite adverse outcomes after elective caesarean section in association with earlier gestational age, and in particular in association with elective deliveries performed prior to 39 gestational weeks. In the mothers, any gestational age modified difference in the risk of an adverse outcome at term elective caesarean section is not clarified. No randomised trials exist of the timing of elective caesarean at term.

**Methods:** From March 2009 to June 2011, we conducted a randomised controlled multicentre open-label trial in seven Danish tertiary hospitals comparing elective caesarean scheduled at a gestational age of 38 weeks and three days versus 39 weeks and three days (in both groups  $\pm$  two days). Women with uncomplicated pregnancies, a single foetus, and a date of delivery estimated by ultrasound were eligible for inclusion. The primary outcome was neonatal intensive care unit admission within 48 hours of birth, and a range of adverse neonatal, maternal, and logistic outcomes were assessed as secondary outcomes. Analyses were by intention-to-treat using Fisher's exact test or logistic regression.

**Results:** We included 1274 women and had a 100% follow-up. There was no significant difference in primary outcome between neonates randomised to elective caesarean section at 38<sup>+3</sup> weeks (88/635; 13.9%) and 39<sup>+3</sup> weeks (76/637; 11.9%), relative risk (RR) 0.86, 95% CI 0.65–1.15. In the 39 weeks group, we found a significant reduction in the incidence of treatment with continuous oxygen for more than one day (RR 0.31, 95% CI 0.10–0.94) and in the incidence of maternal haemorrhage of more than 500 ml (RR 0.79, 95% CI 0.63–0.99). However, these findings were insignificant after adjustment for multiple comparisons. Significantly more women in the 39 weeks group had spontaneous onset of labour and had unscheduled (acute) procedures.

**Conclusion:** Elective caesarean scheduled at 39<sup>+3</sup> weeks did not significantly reduce the incidence of neonatal admission compared to scheduling at 38<sup>+3</sup> weeks of gestation. With adjustment for multiple secondary outcomes, no differences were found in the incidence of secondary neonatal or maternal adverse effects between the two groups.

**Perspectives:** Our results should be supported in future trials. Further research in prediction and prevention of neonatal complications after elective caesarean section would be relevant. Any long-term consequences of elective caesarean timing at term are uncertain.