



Research Question

Primary - For women with a fetus in breech presentation, does early external cephalic version (ECV) (at 34^{0/7}-35^{6/7} weeks) versus delayed ECV (not before 37^{0/7} weeks) increase or decrease the likelihood of caesarean section (CS)?

Secondary - Is the risk of preterm birth (<37^{0/7} weeks) lower or higher with early versus delayed ECV?

Background

Between 3-4% of all term pregnancies will be breech. Recent research indicates that it is safest for babies in a breech presentation to be born by CS. Although most women would prefer a vaginal birth (VB), they will choose CS when there is a medical indication. Most physicians now recommend CS for breech pregnancies. CS remains the largest contributing factor to maternal mortality and serious maternal morbidity associated with birth, and the scar resulting from CS complicates all subsequent pregnancies. Research evidence supports turning breech babies using a technique called external cephalic version (ECV) beginning at 37 weeks gestation to significantly lower the CS rate and thus reduce adverse outcomes for women. Although ECV at term is effective, the procedure is often unsuccessful. A pilot study of early ECV has shown a decrease of 9.5% in the rate of non-cephalic presentation at birth, but before any change in practice can be recommended, it is necessary to confirm these findings, and to determine that beginning ECV early will decrease the rate of CS without any increase in the rate of pre-term birth or serious fetal complications.

Research Design

A multicentre randomised controlled trial design will be used, with stratification for centre and parity. A centrally controlled telephone randomisation service will assign eligible and consenting women to early ECV at 34-35 weeks or delayed ECV at ≥ 37 weeks.

Selection Criteria

Inclusion Criteria:

- Women with any breech presentation
- A live singleton fetus
- Gestational age of 33^{0/7}-35^{6/7} weeks

Exclusion Criteria:

- Any contraindication to ECV
- Any contraindication to early ECV
- Any contraindication to labour or vaginal birth
- Women at increased risk of unstable lie
- Previous participation in the EECV2 Trial.
- Women who wish a vaginal delivery if the fetus remains breech
- Women who wish to deliver by CS if the fetus turns to cephalic

Outcomes

Primary outcome – rate of CS; Secondary outcome – rate of preterm birth; Other outcomes include: admission to neonatal intensive care unit ≥ 24 hours, perinatal or neonatal mortality or serious neonatal morbidity, serious fetal complications, maternal death or serious maternal morbidity, non-cephalic presentation at birth, women's views, and health care costs.

Randomisation

Randomisation will be carried out at 33^{0/7}-35^{6/7} weeks.

Intervention

Prior to randomisation, ultrasound screening will be undertaken to rule out contraindications and confirm presentation. ECV will be done at 34^{0/7} – 35^{6/7} weeks gestation and within 7 days of randomisation in the early ECV group. In the delayed group ECV will be done at or after 37^{0/7} weeks. Tocolytics are recommended to be used for the ECV procedure, either routinely or selectively. The same approach should be used in both groups of the trial. Mothers and babies will be followed until one month after delivery.

Sample Size

In total, 1460 women (730 per group) are required.

Trial Management

Recruitment began in December 2004 and will be completed in December 2008. The trial will involve more than 80 centres internationally and is jointly co-ordinated at the Maternal, Infant and Reproductive Health Research Unit in Toronto and at McMaster University in Hamilton. This study has been funded by the Canadian Institutes of Health Research (CIHR).