

# The BEAD Trial: Baby Head Elevation Device Study at full dilatation caesarean section

ACTRN12624000899549

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Status	RECRUITING
Sponsor	University of Auckland
Enrollment	400 participants

## Plain Language Summary

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When a baby's head has moved deep into the pelvis during labour and an emergency caesarean section is then needed at full cervical dilation, delivering the baby safely becomes much more difficult. This situation — called a full-dilatation caesarean — carries real risks of uterine tears, heavy bleeding, and injury to the baby. The Fetal Pillow is a small inflatable balloon that is placed in the vagina just before the caesarean to gently lift the baby's head back up, making delivery easier and safer.

While many surgeons are already using the Fetal Pillow, this is the first large, double-blinded, independent randomised controlled trial designed to definitively test whether it actually reduces injuries to mother and baby compared to not using it. Half the participants will receive the real device and half will receive a sham (inactive) version, with neither the surgeon nor the patient knowing which was used.

Women aged 16 or older who are having a singleton pregnancy at full term (37 weeks or more), in a head-down position, with confirmed full cervical dilation (10 cm) before emergency caesarean section may be eligible. Women carrying twins, with major foetal abnormalities, known stillbirth before the caesarean decision, or when the surgery is too urgent to allow time for the procedure are not eligible. The trial is run by the University of Auckland.

## Key Eligibility Criteria

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### Inclusion (5)

- Maternal age = /> 16 years
- Singleton pregnancy
- Gestational age =/> 37 weeks
- Cephalic presentation
- Confirmed 10cm cervical dilatation

### Exclusion (4)

- Unable to or don't give consent
- Major congenital anomalies requiring planned NICU admission or palliative care
- Known stillbirth at decision for caesarean section
- Urgency of caesarean section (as determined by operating surgeon) leading to inadequate time to randomise and place the device).

## Locations (1 total)

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Auckland, New Zealand

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000899549>

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