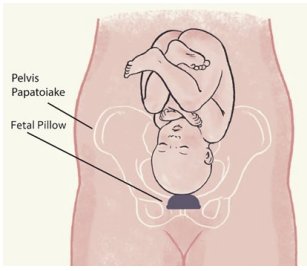
The BEAD Feasibility Study: Baby Head Elevation Device at Full Dilatation Caesarean Section

Jordon Wimsett, Lynn Sadler, Meghan Hill, Charlotte Oyston, Karaponi Okesene-Gafa, Robin Cronin, John Thompson, Erena Browne, Matthew Drake

2-3% of all babies are born via caesarean section at full dilatation (CSFD).



At CSFD the baby's head is often deep in the pelvis which increases the risk of maternal injury, including uterotomy incision tears (or extensions) with increased bleeding, operating time, and future risk of preterm birth. Difficulty in delivering the baby can lead to neonatal asphyxia and trauma[2].

The Fetal Pillow® is a small, soft inflatable balloon placed in the vagina prior to a CSFD and already used widely across New Zealand and Australia.

High quality evidence to support the use of the pillow is lacking[3,4].

Aims

Primary Aim of the Feasibility study: To identify how many patients are offered and willing to participate in a randomised controlled trial of Fetal Pillow® use at fully dilated caesarean section (recruitment).

Primary aim of the BEAD Trial: To determine whether the Fetal Pillow® reduces the rate of maternal uterine incision extensions.

Study Design

The BEAD Feasibility Study is taking place at two maternity units in Auckland, New Zealand over a 12 month period (commenced August 2023) to inform the recruitment strategy and trial processes of a planned, larger BEAD Trial - a placebo-controlled, double blinded, randomised trial which will assess the effect of the Fetal Pillow® at a fully dilated caesarean section on outcomes for mother and baby.

Labour Ward	Operating Theatre		Postnatal ward
Clinical staff: identify women who will undergo CS at full dilatation *Surgeon:* confirms eligibility, obtains abbreviated consent	*Surgeon:* places Fetal Pillow® *Theatre staff:* perform randomisation, **inflation** or **sham-inflation** of balloon	**Birth** *Theatre staff:* perform deflation or sham deflation *Surgeon:* removes fetal pillow® at end of CS, completes data collection template	*Research team:* in-person confirmation of consent (within 3 days of birth). Extract clinical data (to 6 wks postpartum).

Inclusion Criteria

Patients who require an emergency CS:

- Confirmed 10cm cervical dilatation
- Age ≥ 16 years
- Singleton pregnancy
- Gestational age ≥37 weeks
- Cephalic presentation

For more information visit our website via the QR code or email us at thebeadstudy@auckland.ac.nz

SCAN ME

References:

1. Davis, G., Fleming, T., Ford, K., Mouawad, M. R., & Ludlow, J. (25 July 2022). Caesarean section at full cervical dilatation. Australian and New Zealand Journal of Obstetrics and Gynaecology, 55(6), 565-571. https://doi.org/10.1111/ajo.12374

2. Allen VM, O'Connell CM, Baskett TF. 2005. Maternal and perinatal morbidity of caesarean delivery at full cervical dilatation compared with caesarean delivery in the first stage of labour. British Journal of Obstetrics and Gynaecology 112:986–990.

3. 2023. Retraction. Int J Gynecol Obstet. https://doi.org/10.1002/ijgo.14924

4. Lassey SC, Little SE, Saadeh M, et al. Cephalic Elevation Device for Second-Stage Cesarean Delivery: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(4):879-884.

University of Auckland Waipapa Taumata Rau New Zealand

Mercia Barnes Trust — To promote research into Women's Health

hrc nz Health Research Council of New Zealand Te Kaunihera Rangahau Hauora o Aotearoa

Te Whatu Ora Health New Zealand