Participant Information Sheet - Clinicians

Study Title: The BEAD Feasibility Study: A Baby Head ElevAtion Device for fully dilated caesarean sections

You are being asked to take part in the BEAD Feasibility Study

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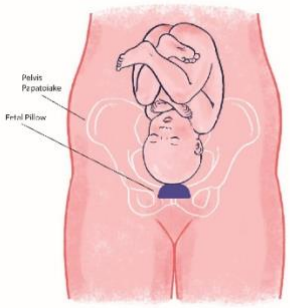
We acknowledge māmā and pēpi as taonga and the significant place they hold within whānau, hapū and iwi as the keepers and preservers of whakapapa. Through this study we hope to determine whether the Fetal Pillow® will improve health outcomes for māmā and pēpi in Aotearoa and globally.

WHAT IS THE PURPOSE OF THE STUDY?

The BEAD Study is looking for people who need a caesarean section in labour at full dilatation (i.e. cervix is 10 cm dilated). We are studying whether a widely used medical device makes birth safer for mothers and babies.

In New Zealand around 1,500 patients undergo a caesarean section at full dilatation each year. Caesarean section at this stage of labour can be associated with increased risks for mother and baby, often due to the baby's head being low in the pelvis at the time of surgery. These risks can be immediate (injury to womb or cervix or baby) or long-term (increased risk of preterm birth in a future pregnancy). There is a medical device called the Fetal Pillow® which is inserted into the vagina before caesarean. The Fetal Pillow® is a soft inflatable balloon that has been developed to try and elevate (lift) baby's head to make delivery easier and reduce the risk of injuries to mother and baby.

Although many maternity hospitals in New Zealand often use this device, there is not enough research to determine whether it reduces the risks associated with full dilatation caesarean . Using the device does not cause any harm to mother or baby, but the device is costly and it takes a couple of minutes to place, so if it is not effective, obstetricians should stop using it.



We are planning a trial to decide whether the device does make birth safe, and whether we should continue to use it.

The purpose of this study is to find out if a large trial of the Fetal Pillow® use is possible. To do this we need to understand whether people will agree to take part, and the things that either prevent or help them complete the study. The information collected in this study will also be included in any larger study of the Fetal Pillow® which occurs as a direct of this study.

WHO CAN TAKE PART IN THE STUDY?

The study will be undertaken at two hospitals: Te Toka Tumai Auckland and Te Whatu Ora Counties Manukau in Auckland, New Zealand.

Participants will be eligible if they are pregnant with one baby that is head down (cephalic) at more than 37 weeks pregnant and need a caesarean section at 10cm dilated.

WHAT DOES THE STUDY INVOLVE FOR PATIENTS?

Patients who agree to take part will have the balloon (Fetal Pillow®) placed in their vagina under the baby's head immediately prior to the caesarean section. This will be done by a member of the surgical team at the same time as insertion of urinary catheter and vaginal preparation. The patient will be randomly allocated to one of two treatment groups.

- Group A: The balloon will be inflated (with 180mLs of water), and then deflated and removed after the baby is born.
- Group B: The balloon will not be inflated, and will be removed after the baby is born.

The patient and the surgical team won't know which group they have been allocated to.

AS A CLINICIAN – WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

<u>O&G Clinician/Surgeon</u>

As a clinician working in obstetrics, we will be asking you to discuss the study verbally with patients in labour who meet the inclusion criteria and if clinically appropriate to obtain abbreviated consent using the provided standardised script. *(Appendix: Abbreviated consent script).* This should take no more than 2 minutes in addition to the usual caesarean section consent.

Once in theatre, you will place the Fetal Pillow® in the vagina as per manufacturers instructions and lay the patients legs flat. While performing your surgical scrub, the anaesthetist will either inflate or sham-inflate the Fetal Pillow®. Both you and the patient will remain blinded as to which group the patient is randomised to. The anaesthetist will deflate or sham-deflate the Fetal Pillow® after you have delivered the baby. You will need to remove the Fetal Pillow® at the end of the procedure. The device is disposable.

The operating surgeon will also be asked to complete a simple form in additional to their operation note *(Appendix: Template tool for recording uterine extensions, operating time and feedback on Fetal Pillow® use).*

To support you in this role, our research team will be providing education around the study itself, standardised education/simulation around use of the Fetal Pillow® as well as teaching around other techniques to manage an impacted fetal head at caesarean section.

Anaesthetist

As an anaesthetist caring for patients who require a caesarean section in labour we will be asking you to help with two aspects of this study.

A member of the anaesthetic team will be involved in the randomisation using the online REDCap database. The randomisation will occur in theatre once eligibility is confirmed by the operating surgeon.

The surgeon is responsible for placing and removing the Fetal Pillow®. We are asking the anaesthetist to either inflate the Fetal Pillow® with 180mLs water (inflation group) or perform a sham-inflation (control group), whilst the surgeon is scrubbing (outside the theatre). Once the baby is delivered, the anaesthetist will deflate the balloon or sham-deflate the balloon. This is to ensure blinding for the patient and surgeon about which group the patient is randomised to.

To support you in this role, our research team will be providing education around the study itself, use of the REDCap database (for randomisation) and standardised education/simulation around use of the Fetal Pillow® (specifically inflating/deflating the device).

WHAT ARE THE BENEFITS OF THE STUDY?

- The results of this study will be used to inform a larger study on the use of the Fetal Pillow.
- The results of this study will be used to improve the care of patients requiring an emergency caesarean section at full dilatation in the future.

WHAT ARE THE RISKS OF THE TREATMENTS?

There have been over 1,300 births reported in the literature with no reports of complications from use of the Fetal Pillow.

WHAT ELSE IS INVOLVED?

As this is a Feasibility Study we are looking to explore barriers and enablers to trial participation for both patients and clinicians. You may be invited to attend an informal focus group with our research team to hear about your experience of participating in the study. Your feedback will help us make any necessary changes before we undertake the larger BEAD Trial.

WHO PAYS FOR THE STUDY?

This research is being conducted by a collaborative group of clinical researchers in New Zealand. Funding is currently provided by the Health Research Council of New Zealand. The medical devices (Fetal Pillows®) used in the study have been purchased from the medical device company (Cooper Surgical) and the company have no role in the design or running of the study. There are no additional costs to you for taking part in the study nor will you be reimbursed for your time.

WHAT ARE MY RIGHTS?

We would really appreciate your help in making this trial a success but taking part is of course completely voluntary. If you choose not to take part then the patients care will not differ from the usual care involved in a caesarean section at present.

WHAT IF SOMETHING GOES WRONG?

We do not anticipate that taking part in the study will increase the participants risk of injury. Patients would be eligible to apply for compensation from ACC in the unlikely event of injury to them or their baby.

WHO DO I CONTACT FOR FURTHER INFORMATION OR IF I HAVE CONCERNS?

Dr. Jordon Wimsett Principal Investigator Phone: 021355828 Email: thebeadstudy@auckland.ac.nz	Dr. Lynn Sadler Co-ordinating investigator, Te Toka Tumai Auckland Email: LynnS@adhb.govt.nz

If you want to talk to someone who isn't involved in the study, you can contact an independent health and disability advocate on: Phone: 0800 555 050 Fax: 0800 2 SUPPORT (0800 2787 7678) Email: advocacy@advocacy.org.nz Website: https://www.advocacy.org.nz/	If you require Māori cultural support, you may contact the administrator for He Kamaka Waiora (Maori Health Team) on: Phone: 09 486 8324 ext 2324	You can also contact the health and disability ethics committee (HDEC) that approved this study on: Phone: 0800 400 569 (Ministry of Health general enquiries) Email: hdecs@health.govt.nz