

Outpatient Balloon vs. Inpatient Gel



The OBLIGE Research Team are excited to share an opportunity with you.

Multiple trials show that initiating IOL with a balloon is safer than, and as effective as, prostaglandins; small trials show that initiating IOL out of hospital is feasible and acceptable. However, low-risk women are not yet offered the option of having a balloon and spending that first 24 hours out of hospital. Outpatient IOL with balloon has not yet been adequately studied for effectiveness and safety.

Our Primary hypothesis is that women having outpatient IOL with balloon will have a lower caesarean section rate, compared to women having inpatient IOL with vaginal prostaglandins.

Our Secondary hypotheses are that when compared to inpatient IOL with prostaglandin gel, outpatient IOL with balloon will not result in increased adverse events for mother or baby; that women having outpatient induction of labour with balloon will be more satisfied; that staff looking after women who are allowed to go home will be more satisfied and that outpatient balloon IOL will be more cost effective.

Inclusion criteria:

Pregnant women with live singleton cephalic presentation

- Planning IOL at ≥ 37 weeks gestation
- Able to remain within one hour of hospital whilst outpatient, if allocated to balloon group
- Able to have with them someone who speaks enough English to communicate with the hospital midwife if concerns, if allocated to balloon group

Exclusion criteria:

- major congenital anomaly;
- suspected fetal growth restriction, as prostaglandins would be contraindicated;
defined as customised EFW $< 3\%$; or customised EFW $< 10\%$ with abnormal dopplers; or abdominal circumference $\leq 5\%$ with abnormal dopplers
- previous caesarean, as prostaglandins would be contraindicated;
- maternal or fetal condition where the clinician feels outpatient care would be contraindicated

How do you include your women in this trial?

- Introduce the Trial when discussing the need for IOL if she meets the Inclusion Criteria
- Refer as per the normal guidelines for IOL ie. Virtual referral or Antenatal Clinic Review.

Who discusses the Trial in-depth with your women?

- If IOL is decided at a specialist appointment and eligibility determined, the trial will be discussed with the patient and an information pack will be given to her at this visit. If she agrees to participate and signs consent form, then consent form will be faxed to DAU along with the IOL booking form. If she prefers to discuss it further with LMC, then she will be asked for permission for Research Team to contact her. The Research Team will then follow up and obtain verbal consent.
- If IOL is booked via Virtual Referrals, then DAU will arrange the booking of the IOL for a morning slot. LMC will be informed of her patient's eligibility to be on the trial and is asked to discuss the OBLIGE TRIAL with her and ask for permission for Research Team to contact her. The Research Team will then follow up and obtain verbal consent.
- Information about the trial is available under the induction of labour tab on the national women's internet site:
<http://nationalwomenshealth.adhb.govt.nz/health-professionals/induction-of-labour>

What happens on the day of induction if my patient has verbally agreed to participate on the Trial

- Your patient and her family will attend Women's Assessment Unit on the day of IOL in the morning at the arranged time, will have written consent obtained, and then will be randomised to either balloon or prostaglandin gel.
- Only woman randomised to the balloon will be allowed to go home, and will receive a written information sheet about when to return and who to ring at WAU if concerned. They will return to Women's Assessment Unit the following morning at 07.30 for removal of the balloon and artificial rupture of membranes.
- If the balloon falls out prior to this then they should remain at home and return as planned at 07.30 the next morning.
- The process will continue as per the normal guidelines with transfer to Labour and Birthing Suite for Syntocinon Augmentation if not in established labour when a Core Midwife is available.
- The prostaglandin Gel induction method remains unchanged

When is the LMC called?

- To provide Labour Cares when the patient is in established Labour.
- Any concerns your patient may have during her stay at home she is to contact Women's Assessment Unit. The number is 09-631-0784.

We look forward to working with you on this Exciting Trial. If you have any questions please do not hesitate to contact us by email **oblige@adhb.govt.nz**