



## Frequently Asked Questions: A resource for pregnant women having induction of labour

### What is the OBLIGE trial looking at?

The OBLIGE study is looking at two different ways of starting an induction of labour. Both are commonly used in New Zealand and around the world, both are safe for mum and baby, and both are effective to start an induction of labour.

We want to find out whether outpatient balloon catheter is a more effective way to start the induction process and reduces the risk of delivery by caesarean section, compared to inpatient prostaglandins (usual care in NZ).

More than 700 women have already participated in the OBLIGE Trial during 2018 and 2019. We need a total of 1550 women to be in the trial, and expect it to continue until 2021. Eleven hospitals around New Zealand are participating in the OBLIGE Trial.

### What are the two ways of starting an induction of labour?

1. Prostaglandin hormone: this is placed in the vagina behind the cervix, either as a gel (that works for 6 hours or more) or a pessary (that works for 12 hours or more). Prostaglandin hormone doses can be repeated as needed until the cervix is soft, thin, open and ready for the next stage of the induction process.
2. Balloon catheter: this is a soft thin tube that is placed through the cervix so that the balloon sits just atop the cervix working with your body's natural hormones and gradually putting pressure on the cervix until it is soft, thin and open and ready for the next stage of the induction process



### Am I eligible?

Most women who are induced after 37+0 weeks' gestation are able to take part in the OBLIGE study. Some common reasons for induction of labour are: diabetes in pregnancy, high blood pressure in pregnancy, going past your due date, having a small baby, or being older than 39.

Sometimes women are not able to take part in the study, for example if you've had a previous caesarean section, your waters have broken, or if there is a concern with you or your baby for which the doctors prefer you to stay in hospital.

If you decide you'd like to take part, the study team will check and make sure you meet all the eligibility criteria, and that the study is a good and safe process for you and your baby.

## **Do I have to take part in this research?**

Participation is voluntary. If you do not wish to take part, you will receive usual care (prostaglandins placed in the vagina at regular intervals and remain in hospital throughout).

If you decide to take part and later change your mind, you are free to withdraw from the trial at any time, even after the induction process has started.

## **What does participation in the study involve?**

- After reading the information sheet, you will have the opportunity to discuss with your partner, family, whanau and midwife or doctor, and to ask questions of the hospital or research staff
- You will then be asked to sign the consent form
- A computerised randomisation procedure (like flipping a coin, there's a 50/50 chance of being in one group or the other) shows which group you will be assigned:
  - prostaglandin hormone and remain in hospital throughout the induction process
  - balloon catheter and be able to go home for the first 18 to 24 hours to wait for the cervix to change and become ready for the next step in the induction process
- After the insertion of either the prostaglandin or the balloon, we will ask you to rate the discomfort during the procedure on a scale from 0-10
- Once you are in labour, the rest of your care is the same regardless of which group you were in, and all decisions about your labour and birth are shared between you and your midwife or doctor
- About 4-6 weeks after your baby is born, we will ask you to complete a short survey that is usually sent out to you by email but can also be done over the telephone if you prefer

## **Can I choose which method I receive?**

The standard method for starting induction of labour at most hospitals in New Zealand is prostaglandin hormones being placed in the vagina at regular intervals until you establish in labour. If you are not in the OBLIGE study, this is how an induction of labour would usually start.

By taking part in OBLIGE there is a 50:50 chance of getting either method; you, hospital staff and LMCs cannot choose. The randomisation process is used to keep the findings scientifically sound. It is similar to flipping a coin. We are using a computer-based system, which allocates women to either the prostaglandin group or balloon group. You won't know until you come into hospital which group you will be in.

Please watch the 4-minute video on the OBLIGE website, which shows how the randomisation works: [www.oblige.auckland.ac.nz](http://www.oblige.auckland.ac.nz)

### **Can I still participate if I don't want to go home?**

No. You need to be willing to receive either method of induction before deciding to participate. That includes going home for 18-24 hours if you are randomized to the balloon group.

If, at any point, there is any concern for you or your baby, you will be asked to stay in hospital. If this happens, you are still part of the trial and your information will still be collected. While at home, if you have any concerns whatsoever you can always contact the hospital team or return to hospital at any time.

### **What if I feel safer in the hospital having a prostaglandin?**

Please be reassured that it is safe to have a balloon, there is a lot of research from around the world that 99.9% of women with a balloon in place do not have anything at all happen to them and don't feel any different and are very satisfied with this method. That's why this study wants to look at women being out of hospital, because balloons are safe and we don't need to do any extra monitoring on mum or baby. In fact, in some hospitals in NZ and Australia, some women are already sent home with balloon in place. This study wants to find out if NZ women prefer this method and if it is more effective than usual care.

### **Will it hurt?**

Vaginal exams: some women find these uncomfortable at this stage in pregnancy.

Vaginal Prostaglandins: some women will experience 'prostin pains'. These can be mild-moderate tightenings, however, these are not contractions. Most women will have regular vaginal exams to monitor if the cervix is changing (softening, thinning and dilating), and CTG monitoring (recording of the baby's heartbeat) to ensure there is no uterine hyperstimulation (5% risk).

Balloon: some women can experience mild period-like pains. This is normal and means the balloon is working. Most women do not feel the balloon once it is in place. There are no extra vaginal exams or CTG monitoring during the next 18-24 hours.

There is a range of experience of pain, with some women feeling nothing at all and others finding exams very uncomfortable. Please discuss options for pain relief with your midwife, such as using nitrous (laughing gas).

### **Which method takes longer?**

Neither the prostaglandin or balloon method have proven to be faster. The timing largely depends on how ready the body is to go into labour.

Often women need more than one dose of Prostaglandins and it is not uncommon for induction process to take up to or longer than 24 hours.

### **What can I expect from the prostaglandin or balloon?**

Both methods are used to start the induction process. Neither is likely to get you into established labour on its own. The aim is to change the cervix (soft, thin, open) to a point that the membranes can be ruptured or that the waters break on their own.

After the membranes are ruptured, then care in labour is decided by the midwives and doctors on the team. Most women having induction will have oxytocin medicine through an IV drip to start or strengthen contractions.

### **What will happen when I arrive for induction?**

On arrival to the ward, the hospital staff first do some assessments to make sure you and your baby are healthy and eligible to participate. This includes checking your vital signs, a CTG monitor of baby's heart rate, and a vaginal examination. If you and baby are healthy and the cervix is not more than 2cm dilated (open), then we can do the randomisation.

After the prostaglandin hormone or balloon catheter is placed, we will repeat the CTG to make sure baby is still healthy. If so, and you received the balloon, you will be able to go home for the next 18-24 hours.

Some hospitals provide vouchers towards parking at the hospital for this visit. Some hospitals offer to pay for a local motel if you want to participate in the OBLIGE study but live more than one hour away from the hospital. Please ask the hospital staff.

### **When do I come back to hospital if the balloon is inserted?**

Before leaving the hospital, we give you an information leaflet. Generally, women come back after 18-24 hours (a time will be agreed upon with the hospital midwife or doctor) to have the balloon removed. If there are any concerns prior, call the hospital midwife on the number provided on the leaflet.

### **What if the initial method doesn't work?**

Sometimes the first method doesn't change the cervix to the point the membranes can be ruptured. In these cases, the other method can then be used. This should not be seen as a failure, but instead as allowing the body more time to prepare for labour. If this happens, you are still part of the study and your information is still collected. The decisions about how to continue the induction process can be discussed with your partner, family, whanau and the hospital team.

### **How will my care be different if I participate in the study?**

The only difference is the process by which induction is started, either with prostaglandins and remain in hospital (the standard of care for inductions) or balloon catheter and go home for the first part of the induction process. The rest of the care during labour and birth will be the same as if you were not participating in the study.

Of interest, it is well known that in general, people who participate in research studies have better outcomes, and hospitals that participate in research have better health outcomes.

**Where can I find out more?**

The OBLIGE website <https://oblige.auckland.ac.nz/> has a link to a short video about the study. It also has as a copy of the pamphlet, the full patient information sheet and consent form, and contact details for all the participating hospitals.