THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Participant Information Sheet

Outpatient Balloon vs. Inpatient Gel

Oblige

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1. Introduction

You are invited to take part in a study comparing two different ways of starting an induction of labour. Induction of labour is the artificial initiation of labour, compared to expectant management of pregnancy where spontaneous labour is awaited. The aim of this project is to find out whether starting an induction of labour with a balloon inserted through the cervix and going home while your cervix prepares for labour, is more effective than, and as safe as, having hormone gel inserted into your vagina and staying in hospital.

Most women in New Zealand will start their induction of labour with one or more prostaglandin (hormone) gel(s) inserted into their vagina every six hours until the cervix is ready for labour. Each vaginal examination can be slightly uncomfortable, but only takes a few minutes. This study will look at whether it is effective and safe for women to start their induction of labour with the insertion of a balloon catheter and going home.

The balloon catheter is a thin, soft and flexible plastic tube. In order to place the balloon through the cervix (neck of the womb), the hospital midwife or doctor will perform a gentle pelvic exam similar to having a smear or swabs taken. A tiny balloon is inflated with about three tablespoons of saline. This puts pressure on the cervix. The placement of the balloon can be slightly uncomfortable, but only takes a few minutes. You should not feel that it is there. It is possible, but uncommon (less than 1%) to experience some vaginal bleeding, uterine tightenings, or ruptured membranes during or just after the balloon insertion. If this does occur, the hospital midwives and doctors will monitor you and the baby, and make a decision together if you should continue to be in the study or not.

Most women in New Zealand would remain in hospital from the moment the induction starts, right through until their baby is born. Women who receive a balloon as part of this study would be able to leave hospital and go home for the first part of their induction. The balloon takes about 18-24 hours to soften the cervix and make the cervix ready for labour.

In order to be able to participate in this study, women will need to meet certain conditions where both the woman and her family/whanau, and the hospital midwives and doctors, feel safe to be at home for the beginning part of the induction of labour. For example, women in the study should have access to a phone, be able to stay within one hour of the hospital, and be able to get transport to and from hospital easily. If you want to participate in the trial, and do not have easy transport, please inform your midwife, doctor or the Research team.

Women will be given a written information pamphlet on what to expect at home, when to return to hospital, what to watch for (for example, leakage of water, vaginal bleeding, decreased fetal movements, or the start of labour and contractions), and how to get in touch with our hospital midwives if there are any concerns. We would not expect any of these to

occur, however, if there are any symptoms or concerns, women can call the hospital Midwife, or return to hospital at any time during the day or night. We would not expect women to start labour at home. Assuming all goes well, women would return to hospital the next morning.

On return to hospital, the balloon will be removed by the hospital midwife. This is not at all uncomfortable.

All women, once they are in labour, will remain in hospital until their baby is born. All women will be looked after during labour and birth by their Lead Maternity Carer (LMC). All women and babies will be monitored closely during labour and birth as per local hospital guidelines. The study will look at whether spending some time during a balloon induction at home improves the chances of having a vaginal birth and reduces the chances of delivery by caesarean section.

Many research studies have looked at starting an induction of labour with a balloon compared to prostaglandin hormone gel(s), and have found it to be safe with no risk of overstimulating the womb and less chance of having heavy bleeding after birth. Some research studies have looked at allowing women to go home for part of their induction of labour with prostaglandin gel(s), and these showed that women were satisfied with being able to go home, got more sleep, and were less worried about their induction. This study will be the first large study in New Zealand to look at allowing women to go home with a balloon for part of their induction of labour.

This trial will recruit over 1,500 women from maternity units across New Zealand over the next two years. Women who need induction of labour at term (37 weeks' gestation or more) will be invited to take part by their own midwife or doctor. The research team will then get in touch with you to provide more information and answer questions.

This form tells you about the study. Knowing what is involved will help you decide if you want to take part in the research project. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with your family/whanau, midwife, or friend.

Participation in this research is voluntary (your choice). If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not. If you decide you want to take part in the study, your midwife, doctor or the research team will ask you to sign the consent form.

2. What does participation in this research project involve?

You will be selected by chance to have your induction of labour with prostaglandin gel(s) and remain in hospital until your baby is born, or to have your induction of labour with a balloon and be able to go home to wait for the cervix to soften. After the insertion of either the gel or the balloon, the midwife will ask you one question to rate the discomfort during the procedure. After your baby is born, we will ask you to complete a short questionnaire. You do not have to answer all the questions, and you may stop the questionnaire at any time.

3. What are the possible benefits and risks?

You personally may not have benefit from participating in this study. We will use the study results to develop better processes for women needing induction of labour in the future.

We do not expect there to be any risks, side effects or discomforts from participating in this study. If you become upset or distressed as a result of your participation, the researcher can arrange for counselling or other appropriate support by staff who are not members of the research team. In addition, you may prefer to stop participating in the study.

There are some risks associated with induction of labour in general (such as cord prolapse, emergency caesarean section, and post-partum haemorrhage). These can occur whether you are participating in this study or having usual care in hospital. These can be discussed in more detail with your midwife and/or doctor. If you have any questions or concerns whilst at home with the balloon, you can ring the hospital Midwife, or come back to the hospital earlier than planned.

If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

4. Do I have to take part in this research project?

Participation in any research project is voluntary (your choice). If you do not wish to take part you don't have to. You will then receive usual care. If you decide to take part and later change your mind, you are free to withdraw from the project at any time. For example, if you have already signed the consent form, but then decide you want to have usual hospital care; or if the balloon is already placed, but you then decide you want to remain in hospital. You can withdraw from the study at any time by speaking to the hospital midwife or doctor looking after you.

5. How will I be informed of the results of this research project?

If you are interested in the results of this research project, go to the website www.nationalwomenshealth.adhb.govt.nz and look under the heading "Research". Alternatively, we can email you a summary of the results if you provide us with your email address on the consent form.

6. What will happen to information about me?

No material that could personally identify you will be used in any reports on this project. Information obtained from the questionnaires and from your health records held at the hospital will be entered into a secure database where it will be anonymous and confidential. Information will be kept for 10 years and then discarded in an appropriate way.

7. Is this research project approved?

Ethics approval has been given by the Central Health and Disability Ethics Committee.

The study has been registered with the Australian New Zealand Clinical Trials Registry.

8. Who can I contact?

If you want any further information concerning this study, you can contact the principal researcher Dr Michelle Wise on 09-373-7599 x 89488 or c/o Department of Obstetrics and Gynaecology, FMHS, University of Auckland, Private Bag 92019, Auckland 1142, or Email oblige.study@auckland.ac.nz

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate on Free phone: 0800 555 050; or Free fax: 0800 2787 7678; or Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on: Phone: 0800 4 ETHICS or Email: hdecs@moh.govt.nz

If you require Māori cultural support talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 4868324 ext 2324. If you have any questions or complaints about the study you may contact the Auckland District Health Board Maori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext 3204.