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**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Master document]*

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| --- | --- |
| **Title** | OptiMising induction of labour care: oral misoprostol versus balloon dilatation – Study 1 |
| **Short Title** | *OptiMis-IO-1* |
| **Principal Investigator** | Dr Rachael Nugent  |
| **Co Investigators** | Associate Professor Lauren KearneyDr Jane MaherDr Nigel Lee Dr Xin Yu (Adeline) Foo Dr Emma SeedDr Christoph Lehner Dr Tegan TriggsDr Bec JenkinsonAssociate Professor Emma Ballard |
| **Location**  | [Insert on site specific PICF] |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you are pregnant and are planning to have an induction of labour. The aim of this project is to find the best way to test different approaches to labour induction. Our standard way of inducing labour is via a balloon catheter or vaginally administered hormone gel, inserted through or behind, respectively, your cervix. There is now a new approach to induction which requires women to take an oral tablet regularly over 1-3 days to start their labour.

This Participant Information Sheet and Consent Form tells you about this research project. You can use it to decide if you want to take part.

Please read this information carefully. You can ask questions at any time. You may also like talk about it with a relative, friend or your maternity care provider. Participation in this research is voluntary. 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 to take part in this research project, you will be asked to sign a consent form. By signing it you are telling us that you:

• Understand what you have read,

• Consent to take part in the research project,

• Consent to have the tests and treatments that are described, and

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Induction of labour is the process of starting labour artificially. There are two main ways that we currently do this in Queensland:

* *Balloon catheter*. A midwife or doctor inserts a soft, thin tube (catheter) into your vagina and through your cervix. One or two balloons at the end of the catheter are filled with water. The balloon helps your cervix to soften and open and is usually left in for at least 12 hours. When your cervix is open enough, the membranes around your baby can be broken (waters broken). You can then be given a medicine through an intravenous “drip” to bring on contractions.
* *Artificial prostaglandins.* Prostaglandins are a hormone produced naturally by the body to prepare the cervix for labour. An artificial copy of this hormone can be used to soften and open your cervix. These artificial prostaglandins are applied to your cervix, as a gel or pessary (like a tampon). This process is repeated about every 6 hours and may take around 12-24 hours to work. When your cervix is open enough, the membranes around your baby can be broken (waters broken). You can then be given a medicine through an intravenous “drip” to bring on contractions.

We would like to trial another way of inducing labour, known as “low-dose, oral misoprostol”. In this method, you will come to hospital in the morning, have an assessment of your and your baby’s wellbeing, and then start taking a tablet regularly (2-4 hourly) until either your contractions become regular, or your cervix opens enough for your waters to be broken and start the hormone drip to bring on contractions. This may take 1-3 days, and you will stay in hospital for this time. This tablet is used widely in Europe and New Zealand and has been found to be safe.

We would like to find the best way to implement this approach and to find out if it is acceptable to Australian women.

**3 What does participation in this research involve?**

You are invited to take part in this study because:

* you are at least 18 years old,
* you are pregnant with a single baby who is head-down,
* you are planning a vaginal birth, with your labour induced,
* your waters have not broken yet and your cervix is not already open enough to ‘break your waters’,
* your baby has a normal heartbeat,

you have not been diagnosed with any medical condition that would exclude you from this study.

You do not have to take part in this study. It is completely voluntary. If you decide not to take part, it will not affect your health care within the hospital in any way. If you choose to take part, you will be asked to sign a consent form, after reading through this information.

If you decide to take part, you may receive either the usual method of induction of labour or the new method. Neither you, your maternity care provider or the research team gets to decide which group you will be in. You will have a 1 in 2 chance of being in either group. Every participant is put into a group by chance (random).

All participants will also be asked to complete a survey 2-4 weeks following birth. We will send you a link to a brief online survey, via text message or email. This will take approximately 10 minutes to complete, and you can commence it, and come back to finish it later if need be. The surveys will ask questions about:

* Whether the way your labour was induced was acceptable to you
* Your birth experience

We will also access your electronic health records to collect clinical information about your pregnancy, labour and birth, such as your baby’s birth weight, gestation, mode of birth and other routinely collected data.

We would also like to collect a small blood sample from your baby’s umbilical cord after they are born. Your baby will not ‘feel’ this, and it does not require early cord clamping. This blood test will be undertaken in the birth suite soon (usually within an hour) after your baby is born and analysed on a machine in the birth suite. No blood tests directly from your baby will be required for this study.

There are no additional costs associated with participating in this research project, nor will you be paid. All tests and medical care required as part of the research project will be provided to you free of charge.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way. This supports study clinicians and participants to remain open to the true results.

**4 Other relevant information about the research project**

We aim to recruit 140 women to this study overall, with 70 ‘usual care’ and 70 ‘inpatient oral misoprostol’ arms. We anticipate this will take 6-9 months. This study will be led and locally conducted in South-East Queensland, by a team of experienced obstetricians, midwives, consumers, and University of Queensland researchers.

**5 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any time, without penalty.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the hospital caring for you.

**6 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include a better induction of labour experience, with fewer vaginal examinations.

This study is the first of its kind. If it is successful, we will continue on to a much larger study to determine the best method of induction of labour for women and their babies.

**7 What are the possible risks and disadvantages of taking part?**

Low-dose, oral misoprostol has been TGA approved for use in Australia when inducing labour and is safe. It is routinely used in New Zealand and Scandinavia. However, medical treatments may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk to your midwife, during labour.

Your study doctor and midwife will also be looking out for side effects.

* >10% of women experienced meconium-stained liquor (where your baby does a ‘poo’ whilst in utero) postpartum bleed.
* >1% and <10% of women experienced nausea and vomiting and some chills/shivers
* >0.1% and <1% (very uncommon) baby’s heart rate was abnormal during labour in connection with hyperstimulation (>5 contractions per 10 minutes)

If you become upset or distressed because of your participation in the research, the study doctor or midwife will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

**8 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you decide to withdraw, we will not collect additional personal information from you. Personal information already collected about you can also be withdrawn. If you do not want this data to be retained, you must tell us when you withdraw from the research project.

**Part 2 How is the research project being conducted?**

**9 What will happen to information about me?**

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Each participant will be given a unique study number, known only to the research team. This number will be used to make all data collected anonymous. Data will be stored for 15 years, in password protected files within the University of Queensland and Queensland Health. No identifying information will be shared. Only named research team members will have access to the information. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, we will present information so that you cannot be identified.

If you consent to participate in this trial, this will be recorded in your hospital record.

**10 Complaints or distress**

If you suffer any harms or complications because of this research project, you should contact the study team as soon as possible. We will assist you to arrange appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Sometimes thinking about the sorts of things we ask you in the survey can create some uncomfortable or distressing feelings. If you need to talk to someone about this immediately, please contact Lifeline on 13 11 14. You may also wish to consider consulting your General Practitioner (GP) for additional support or contact BirthTalk (<http://birthtalk.org>) or BeyondBlue (https://www.beyondblue.org.au).

**11 Who is organising and funding the research?**

This research project is being conducted by Dr Rachael Nugent and team. It is being funded through a research grant, awarded by the Study, Education, Research Fund, Sunshine Coast Hospital and Health Service.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**12 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Metro North Health. The University of Queensland research committee has also approved this study (insert number once ratified).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**13 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project you can contact the principal study investigator: Dr Rachael Nugent on 0413 904 205 or any of the following people:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | Rachael Nugent  |
| Position | Obstetrician and Gynaecologist  |
| Telephone | 0413 904 205 |
| Email | Rachael.Nugent@health.qld.gov.au  |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints and governance contact person**

|  |  |
| --- | --- |
| Position |  |
| Telephone |  |
| Email |  |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Metro North Health HREC A |
| Telephone | (07) 3646 5280 |
| Email | MetroNorthResearch-Ethics@health.qld.gov.au  |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | OptiMising induction of labour care: oral misoprostol versus balloon dilatation within a stratified inpatient to outpatient setting |
| **Short Title** | The OptiMis-IO study |
| **Project Sponsor** | SERTF |
| **Coordinating Principal Investigator/****Principal Investigator** | Dr Rachael Nugent  |
| **Associate Investigator(s)** | Associate Professor Lauren KearneyDr Jane MaherDr Nigel Lee Dr Xin Yu (Adeline) Foo Dr Emma SeedDr Christoph Lehner Dr Tegan TriggsDr Bec JenkinsonAssociate Professor Emma Ballard |
| **Location**  | [to be inserted]  |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the research team concerning my clinical outcomes (such as mode of birth and other routinely collected data), for the purposes of this project. I understand that such information will remain confidential.

I give permission for a small amount of blood to be collected from my baby’s umbilical cord after they are born (but not within 1 minute of birth to facilitate delayed cord clamping) Yes ¨ No ¨

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care. I understand that I will be given a signed copy of this document to keep.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | OptiMising induction of labour care: oral misoprostol versus balloon dilatation within a stratified inpatient to outpatient setting – Study 1 |
| **Short Title** | OptiMiso-IO-1 study  |
| **Project Sponsor** | SERTF  |
| **Coordinating Principal Investigator/****Principal Investigator** | Dr Rachael Nugent  |
| **Associate Investigator(s)** | Associate Professor Lauren KearneyDr Jane MaherDr Nigel Lee Dr Xin Yu (Adeline) Foo Dr Emma SeedDr Christoph Lehner Dr Tegan TriggsDr Bec JenkinsonAssociate Professor Emma Ballard |
| **Location**  | [to be inserted]  |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the hospital.

I wish to leave the study ¨ I wish to withdraw my data from the study ¨

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**Declaration by Study Doctor/Senior Researcher**

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

Note: All parties signing the consent section must date their own signature.