PATIENT LABEL

*Insert Header with institution’s name or institution’s letterhead*

**Participant Information Sheet/Consent Form**

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

|  |  |
| --- | --- |
| **Title** | **ASAPP: Azithromycin for Short cervix and Amniotic fluid sludge for the Prevention of Preterm birth, a pilot randomised controlled trial** |
| **Project Sponsor** | TBA |
| **Coordinating Principal Investigator** | A/Prof Joanne Said  |
| **Principal Investigator** | *[Principal Investigator]* |
| **Associate Investigator(s)** *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location]* |

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

1. **Introduction**

You are invited to take part in this research project. This is because you have risk factors which make it more likely that your baby will be born early, known as “preterm”. This research project is testing a treatment which may help to prevent preterm birth. The treatment is an antibiotic, called azithromycin.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

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 a relative, friend or your local doctor.

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 or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. 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

• 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?**

Babies born early (“premature” or “preterm”) are more likely to need care in a Special Care Nursery or Neonatal Intensive Care Unit (NICU). There are many risk factors which make it more likely that your baby will be born early, but two important risk factors include having a short cervix (“neck of the womb”) and amniotic fluid sludge (“sludge”), a finding seen on ultrasound. “Sludge” is material found inside the amniotic sac. The amniotic sac is the sac of fluid your baby grows in. The exact nature of “sludge” is not known, however scientists believe it is associated with infection. Having both a short cervix and “sludge” increases the risk of having your baby early.

The aim of this study is to find out if azithromycin is an effective treatment for amniotic fluid sludge. Azithromycin is a type of antibiotic medication commonly used to treat many different types of infections. In some previous studies, the use of azithromycin has appeared to prolong pregnancy in women with “sludge”. However, in other studies the benefit of giving azithromycin is less clear. There are currently no studies that show how effective azithromycin is for treating “sludge” specifically. We hope that the results from this study will help us develop a bigger trial which will directly assess the impact of azithromycin in reducing the risk of preterm birth.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Azithromycin is approved in Australia to treat a variety of different infections, including lung/respiratory infections, sexually transmitted infections and gut infections. However, it is not approved to treat amniotic fluid sludge. Therefore, it is an experimental treatment for “sludge”. This means that it must be tested to see if it is an effective treatment to eliminate “sludge”. We know that is it safe to be given in pregnancy and does not carry any risk of causing birth defects.

This research has been initiated by the study Doctor, Associate Professor Joanne Said who is a specialist Obstetrician.

This study is a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. You might receive azithromycin tablets or you might receive placebo tablets. A placebo is a medication with no active ingredients. You will not know which group you are in. The doctors, nurses and midwives will not know which group you are in. The results are compared to see if azithromycin tablets are better. To try to make sure the groups are the same, each participant is put into a group by chance (random–like tossing a coin).

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

To determine whether you are able to participate in this study, study doctors will first conduct an assessment. This is called “screening”. During the screening process you will be asked some questions to make sure you are eligible to take part. Study doctors will also need to confirm the length of your cervix and assess for “sludge”. This is done using an internal ultrasound probe inserted into the vagina. At this initial visit, a swab will also be collected from the cervix to investigate for the presence of bacteria.

If you agree to participate in the study, you will be asked to sign a consent form. The consent form will be signed prior to any study assessments being performed.

The research midwife will then use a computer program to randomise you to receive either azithromycin tablets or placebo tablets. Randomisation is a way of randomly allocating you to receive either the azithromycin tablets or placebo tablets. The placebo we are using is very safe for both you and your baby.

There is a 50:50 chance you will receive the azithromycin tablets. This is a “double-blind” study. This means that neither you nor your study doctor, nor the midwives or doctors caring for you will know which treatment you are receiving. This research project has been designed to make sure that the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Regardless of which group you are in, you will take a course of tablets by mouth for five days. You are able to take the tablets at home. If you are in the azithromycin group, you will take two 250mg tablets on the first day, and a 250mg tablet each day for the next four days. If you are in the placebo group, you will take two placebo tablets on the first day and a placebo tablet each day for the next four days. You will not be able to tell whether you are taking the azithromycin tablets or the placebo tablets, as they are designed to look and taste the same.

After you have finished taking the tablets, we will ask you to return for follow-up. The first follow-up appointment will be two weeks after you enrol in the study. During this visit, we will use an internal ultrasound transducer through the vagina to check for amniotic fluid sludge and to measure the length of your cervix. You will also be given a short questionnaire to complete. The questionnaire will collect information about any symptoms you might have noticed since taking the tablets. This should only take about 5 minutes.

We will also collect a swab to look for bacteria. When you are 26 weeks’ pregnant, you will have another ultrasound inside the vagina to measure the length of your cervix and another swab will be collected.

After the birth of your baby, the research midwife will collect information about your pregnancy and the birth from your medical records. The midwife will also collect information about your baby from your baby’s records. We will only collect data up until the time you and your baby leave hospital.

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

You will receive a parking voucher to cover the costs of attending the 3 study visits (the first visit, the visit after 2 weeks and the visit at 26 weeks’ gestation) associated with the research project visit.

**4 What do I have to do?**

There are no specific lifestyle changes that you will need to make as a participant in this study. You may engage in all your usual activities unless otherwise directed by your doctor. You may eat a normal diet. It is important to tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health shop. This is because some medicines and azithromycin may interfere with each other, and this may restrict you from participating in the study.

You may not be able to participate in this research study if you are allergic to azithromycin or have certain heart conditions. If you choose to participate in this study, it is important that you understand that you have a responsibility to take the tablets regularly and in accordance with the instructions provided. You will also need to continue to attend any scheduled hospital visits for your pregnancy.

If you have any concerns about your health or your baby’s health, it is important that you contact the hospital and follow the advice of the doctors and midwives caring for you. The staff caring for you at the hospital will be aware that you are taking part in this study as we will make a note about this in your medical record. The staff won’t know which group you have been allocated to (azithromycin or placebo).

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

In this study we hope to recruit 84 participants across multiple hospitals. These include Joan Kirner Women’s & Children’s at Sunshine Hospital, The Royal Women’s Hospital, Eastern Health and Monash Medical Centre. These are all major maternity service providers in Victoria. This trial is a “pilot” trial, meaning that a larger more definitive trial may follow on from this study in the future. This project will involve researchers from a number of organisations working in collaboration.

**6 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 stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

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 *[Name of Institution].*

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Other treatments are available and will remain available should you choose to participate in the study. Vaginal progesterone and cervical cerclage (a stitch in the cervix) are two treatments which have been shown to be effective in reducing the rates of preterm birth in women with short cervix. These treatments will remain an option to you if they are needed regardless of whether or not you choose to participate in the study.

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

We cannot guarantee or promise that you or your baby will receive any benefits from this research; however, by participating in this study you will be making an invaluable contribution to research in women’s and newborn’s health which may benefit other women and their babies in the future.

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

Medical treatments often 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 with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

The side effects that you might experience include:

* **Nausea, vomiting, diarrhoea, abdominal pain/cramping, candida (thrush) infection.** These side effects occur in less than 5 in 100 people (less than 5%) who are taking azithromycin. These symptoms are usually mild.
* **Rash, headache.** These side effects occur infrequently, in less that 1 in 100 people (less than 1%) who are taking azithromycin.
* The following side effects are rare, occurring in less than 1 in 1000 people (less that 0.1%) who are taking azithromycin:
* **Hypersensitivity** (undesirable reactions produced by the normal immune system, including allergies and anaphylaxis)
* **Mental health problems**
* **Toxicity to the ear** causing ringing in the ear, dizziness or hearing loss
* **Liver problems**
* **Pancreatitis** (inflammation of the pancreas)
* **Prolonged QT interval** (abnormal heart rhythm)
* **Abnormal blood count**

Serious but very rare side effects include irregular heart rhythm (“arrhythmia”). The specific conditions thought to be associated with azithromycin are called “QT prolongation” and “Torsades de Pointes”. These very rare heart conditions were reported in a study which suggested oral azithromycin is associated with increased risk of death from a heart-related cause, and an increased risk of death from any cause. This observed risk is small, and most significant in people who have other risk factors for heart disease. To minimise the risk to you and your baby, you will not be able to take part in this study if you have a personal history of Congenital long QT syndrome, Torsades de Pointes, arrhythmia, or uncompensated heart failure.

If you become upset or distressed as a result of your participation in this research, the study doctor 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.

**10 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

**11 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

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

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results from the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them when you withdraw.

**13 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• Unacceptable side effects

• Azithromycin being shown not to be effective

• Azithromycin being shown to work and not need further testing

**14 What happens when the research project ends?**

The researchers will analyse the results and decide whether we should proceed to the larger study. We may publish the study results in a scientific journal. If you wish, the researchers can send you a summary of the results.

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

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

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Any information obtained in connection with this research project that can identify you will remain confidential. All information will be stored on password protected databases which are located on a secure server at The University of Melbourne. All paper copies of information about you will be stored in locked filing cabinets. 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, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project will be recorded in your health records so that the doctors and midwives caring for you are aware that you are participating in this study.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

All information will be stored in accordance with the relevant legislation for a period of 25 years following the completion of the study. After this time, all paper files will be destroyed via secure shredding. All electronic files will be permanently deleted.

**16 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging 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.

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

This research project is being conducted by Associate Professor Joanne Said. There is no commercial funding for this research. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**18 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 Melbourne Health. Approval to conduct this research at Joan Kirner Women’s & Children’s Sunshine Hospital has been provided by the Western Health Office for Research.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research 2007 (updated 2018). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**19 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 or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *[Phone number]* or any of the following people:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone]* |
| Email | *[Email]* |

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

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone]* |
| Email | *[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 | Royal Melbourne Hospital HREC |
| HREC Executive Officer | Manager HREC |
| Telephone | (03) 9342 8530 |
| Email | research@mh.org.au |

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

*Insert Header with institution’s name or institution’s letterhead*

PATIENT LABEL

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

|  |  |
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| **Title** | **ASAPP: Azithromycin for Short cervix and Amniotic fluid sludge for the Prevention of Preterm birth, a pilot randomised controlled trial** |
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| **Coordinating Principal Investigator** | A/Prof Joanne Said  |
| **Principal Investigator** | *[Principal Investigator]* |
| **Associate Investigator(s)** *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location]* |

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**Consent Agreement**

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 *[Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

PATIENT LABEL

**Declaration - for participants unable to read the information and consent form**

|  |
| --- |
| Declaration - for participants unable to read the information and consent formWitness to the informed consent processName (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**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.

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

† 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.

A copy of the plain language summary of the findings of this study will be made available to participants. Would you like to receive a copy of the plain language summary at the conclusion of the study? Please include an email address if you wish to receive this.

🞏 Yes - Please include an email address below.

🞏 No

Email address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PATIENT LABEL

*Insert Header with institution’s name or institution’s letterhead*

**Form for Withdrawal of Participation**

|  |  |
| --- | --- |
| **Title** | **ASAPP: Azithromycin for Short cervix and Amniotic fluid sludge for the Prevention of Preterm birth, a pilot randomised controlled trial** |
| **Project Sponsor** | TBA |
| **Coordinating Principal Investigator** | A/Prof Joanne Said  |
| **Principal Investigator** | *[Principal Investigator]* |
| **Associate Investigator(s)** *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location]* |

**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 *[Name of Institution].*

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

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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