**Participant Information Sheet/Consent Form**

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| **Title** | Role of vaginal antiseptic prior to Caesarean Section in reducing Post-Caesarean complications: A blinded randomised controlled trial | |
| **Protocol Number** |  |
| **Principal Investigator** | Dr Monika Trivedi |
| **Co-Investigator(s)** | Dr Kishor Singh, Dr Md Rafiqul Islam, Dr Ainsley Robinson |
| **Study Location** | Department of Obstetrics and Gynaecology, GV Health |

**1 Would you like to take part in this research study?**

We would like to invite you to take part in our research study. This is because you are expecting to give birth and is might undergo either emergency or elective caesarean section (a well-known operative procedure to bring the baby out by cutting your tummy) at GV Health Obstetrics and Gynaecology Department. Although this research study focusses on delivery by caesarean section and not by vagina (both elective and emergency caesareans), we are inviting all expecting pregnant women, who want to be booked for caesareans or being admitted to the birthsuite for vaginal delivery, since there is 20-30% chance of emergency caesarean delivery with intended vaginal delivery (as it is mostly unpredictable).

This Information Statement tells you about the research project. It explains the procedures 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, obstetrician 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 to go ahead, we will ask you to sign the consent form (the last page of this document).

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

Caesarean section can have ten times higher risk of infections than that of vaginal delivery. This can lead to prolonged hospital stays and a significant delay in return to normal function causing burden on the mother, the infant, and the health care system.

Although the current post-caesarean infection is quite low in GV Health, cleansing the vagina with an antiseptic solution before a caesarean delivery can reduce the likelihood of post-caesarean infections further. However, different antiseptics or cleansing with nothing have been practised inconsistently and there is no clear evidence supporting which vaginally administered antiseptic solution is the most effective for preventing post-caesarean infections.

In this study, we want to identify which vaginal cleansing antiseptic solution is most effective for reducing the incidence of maternal post-caesarean infections.

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

After careful reading and appropriate understanding of this information statement, a consent form must be signed prior to enrolling a participant in the study. This research involves ante-natal women undergoing elective or emergency caesarean delivery who do not have any signs of different types of infection. Informed consent may be obtained from every woman during booking (for elective caesarean section), irrespective of their mode of delivery including emergency caesarean patients that are initially booked for vaginal delivery. If vaginal delivery is successful and emergency caesarean delivery is not necessitated, the obtained consent is not applicable and the patient will not be enrolled in the study.

Once enrolled, you will be assigned to one of the following three vaginal cleansing groups on an equal chance basis. Therefore, you will have a one in three chance of receiving intervention A or intervention B or no intervention C (Control):

1. Povidone Iodine (1% povidone iodine solution), one type of antiseptic solution
2. Chlorhexidine, another type of antiseptic solution
3. Control – no vaginal cleansing

A control group helps us to be confident that effects we measure in the other groups really are due to the antiseptic solution. This is a blinded study where you will be unaware of the type of cleansing treatments that you are receiving but your study doctor or treating team.

***Procedures***

After obtaining written informed consent, you will pick-up a sealed envelope at random containing either an intervention (as A or B) or control (C). You will pass the envelope to the treating team and the treating team will apply the vaginal cleansing agent as per the allocated treatment in the envelope.

Immediately prior to your elective or emergency caesarean delivery, you will receive the vaginal cleansing procedure with the allocated intervention or no intervention (Control). The procedure will be performed by the doctor performing the delivery once anaesthesia is given, just prior to commencing emergency or elective caesarean section. Hence, you will not feel anything as you already have the anaesthesia.

This research study will also collect the following information about you and your caesarean delivery either from your patient record or from you directly telephonically on the 14th and 28th post-operative days:

* Socio-demographic characteristics
* Required clinical and pregnancy related information
* Fever, infection and readmission related information, such as
  + Duration of artificial rupture of membranes (ARM)/spontaneous rupture of membranes (SROM)
  + Duration of labour
  + Body mass index (BMI) measured from your height and weight
  + Presence/management of Diabetes during the pregnancy with current diet, conservative management or insulin regime
  + Duration of Surgery (caesarean section)
  + Estimation of blood loss (EBL)
  + Previous caesarean section (1/2/3) of elective/emergency nature
  + Vaginal Examination at caesarean section

***Additional costs***

There are no additional costs associated with participating in this research project, nor will you be paid.

**4 Do I have to take part in this research study?**

Participation in this research study 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 Sheet/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 GV Health.

**5 What are the possible benefits and risks of taking part in this research study?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include a reduced risk of post caesarean delivery infections.

There are no anticipated risks or side effects or minimal side effects such as minor allergic reactions in terms of transient itching may happen (very rarely) in participating in this study. The principal investigator and the other investigators will maintain a routine and close monitoring of the study activities. However, although the proposed interventions are safe, if any study participant is found sick during study conduction, the investigators will provide adequate suggestions or refer to or provide support on care seeking from appropriate areas of healthcare as per routine standard protocol.

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

By signing the consent form you consent to the research study staff collecting and using personal information about you for the research project.

Any information obtained in connection with this research study that can identify you will remain confidential. No identifiable information will be used but an aggregated data for dissemination. You will be allocated a participant number for de-identification purposes.

All data collected will be kept securely within the GV Health network. No other than study investigators will have access to the data. All data will be stored with the PI in a GV Health password protected computer for a period of 05 (five) years.

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 study will be published and/or presented in a variety of forums. In any publication and/or presentation, data and information will be provided in such a way that you cannot be identified.

Information about your participation in this research project may be recorded in your health records. Any hard copies of the data will be shredded/destroyed and disposed of in GV Health’s confidential paper/document collection bins and all soft copies of the data will be permanently deleted from the computer once the data storage time is over or at the conclusion of the study.

**7 Who is conducting and paying for this research study?**

This research study is an unfunded investigator-initiated project conducted by Dr Monika Trivedi, Consultant Obstetrician and Gynaecologist, and the study is sponsored by the Obstetrics and Gynaecology Department, GV Health.

**8 Who has reviewed the research study protocol and procedures?**

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 GV Health and the approval number is GVH 22/20.

This project will be carried out according to the Good Clinical Practice guidelines and the National Health and Medical Research Council’s 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.

**9 Who do I contact if I have a question or complaint?**

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

If you would like any further information concerning any aspects of this research study or if you have any medical problems which may be related to your involvement in the study, you can contact the principal investigator, Dr Monika Trivedi, on Ph: 5832 3080 or E: [monika.trivedi@gvhealth.org.au](mailto:monika.trivedi@gvhealth.org.au).

If you have concerns about your rights as a participant in this research, or have a complaint about the manner in which the research is conducted, please contact the Chair/Deputy Chair, GV Health Human Research Ethics Committee on either [research.ethics@gvhealth.org.au](mailto:research.ethics@gvhealth.org.au) or 58310110.

**Consent Form**

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| **Study Location** | Department of Obstetrics and Gynaecology, GV Health |

**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 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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| **Declaration by Participant – for participants who have read the information** | |
| Name of Participant (*please print*): | |
| Signature: | Date: |
| **Declaration by Participant – for participants unable to read the information and consent form** | |
| *Witness to the informed consent process*  Name (*please print*): | |
| Signature: | Date: |
| **Declaration by Investigator/Doctor** | |
| I have given an adequate verbal explanation of the research study, its procedures and risks and I believe that the participant has understood that explanation written in the Information Statement.  Name (*please print*): | |
| Signature: | Date: |

**Withdrawal of Participation Form**

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| --- | --- |
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**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 *GV Health.*

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

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|  | | | | | | |
|  | 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.