

INFORMATION SHEET AND INFORMED CONSENT FORM

**EFFICACY OF PC6 ELECTROACUPUNCTURE IN THE PREVENTION OF
NAUSEA VOMITING IN CAESAREAN PATIENT UNDER SPINAL ANAESTHESIA**

NMRR ID: 19-3279-51524(IIR)

Date: 4th MARCH 2020

Sponsor: Self-sponsored study

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

1. **Title of study:** PC 6 Electroacupuncture in the prevention of nausea vomiting in caesarean patient under spinal anesthesia.
2. **Name of investigator and institution:** Dr Chan See Yun (KKM, HRPB)
Dr Lee Chek Ning (KKM HRPB)
Dr Muhamad Rasydan bin Abd Ghani (IIUM)
3. **Name of sponsor:** self-funding

4. Introduction:

You are invited to participate in a research study because you are at term pregnancy that requires lower section caesarean section. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your doctor with information on your health history; you may harm yourself if you are not truthful with the information provided.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. What is the purpose of the study?

The purpose of this study is to compare PC6 electro-acupuncture plus granisetron with granisetron plus sham acupuncture in the prevention of nausea vomiting in LSCS patient under spinal anesthesia. This research is necessary because nausea and vomiting incidence are both high in caesarean section patient even with common practice of single prophylaxis treatment. Granisetron is the 5HT₃-antagonist drug, which is known to be effective in prevention of nausea vomiting as well as treatment, but with medication alone the incidence of nausea vomiting is still as high as 50% and its safety in pregnancy and breastfeeding is questionable. Whereas PC6 is an acupuncture point known to be effective to prevent nausea vomiting as non-pharmacological method. We are hoping with the combination of both methods will further reduce the incidence of nausea vomiting in caesarean section patient.

A total of 98 subjects like you who undergo caesarean section will be participating in this study; All will be done in hospital Raja Permaisuri Bainun. The whole study will last about 4 months and your participation will be about 24 hours (the moment you are given spinal anesthesia until post-operative 24 hours)

6. What kind of drugs and procedure will I receive?

If you agree to participate in the study, the doctor may need to access your medical history to determine if you are suitable for the study. If you are deemed suitable, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below, PC6 electroacupuncture plus granisetron group or granisetron plus sham acupuncture group. You have equal chance of being assigned to each of the groups. This is a double-blinded study, you will not know if you have received a electroacupuncture or sham acupuncture during operation. The assessor in the ward will not know which group you are in as well.

The study products do not contain porcine, bovine or animal components.

Group 1: PC6 electroacupuncture plus granisetron 1mg (EA group)

Group 2: Sham acupuncture plus granisetron 1mg (sham group)

7. What will happen if I decide to take part?

- a) If you are in sham group, you will receive acupuncture inserted at 2 points each hand (non-acupoint, placebo point or sham point) after given spinal anesthesia and in supine position (figure 3). Non acupoint means the point in the body not known to have acupuncture effect if it is punctured.
- b) If you are in EA group, you will receive the acupuncture needles inserted at bilateral Pericardium Meridian point 6 (PC6) and large intestine meridian point 4 (LI4) (Figure 1) after given spinal anesthesia and in supine position.
- c) The needles will be inserted by a trained acupuncturist using a “flicking in” technique with a needling guide tube to ensure it is at an appropriate depth (0.5-1 cun) The EA needles were stimulated before the start of surgery until the end of surgery at a frequency of 2 Hertz that was produced by electronic Acupuncture Treatment Instrument registered under medical device authority (Figure 2), whereas in sham group electrode will be connected but no stimulation will be applied.
- d) This device used alternating current (AC) for a substantial step-down in voltage and amperage and ensured that there was virtually no current transmitted through the patient’s body for intraoperative safety.
- e) The proximal and distal electrodes were clipped on to the sterile single use acupuncture needles.
- f) Stimulation will be stopped and needles will be removed at the end of surgery.
- g) You will usually feel mild discomfort at the skin site during needle insertion and stimulation.
- h) You will be monitored and asked with few questions during and 24 hours after operation.

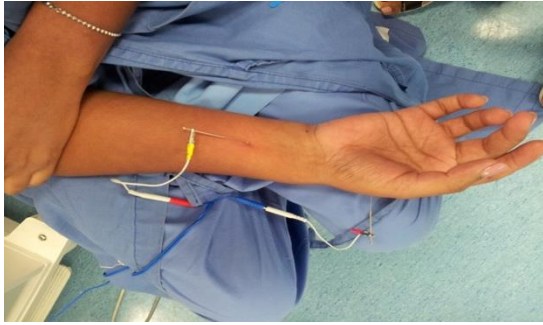


Figure 1



Figure 2



Figure 3

8. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the study doctor. There may be certain medications that you cannot take while participating in this study. The doctor will discuss those medications with you. You must not take any other medications without consulting your study doctor. You must inform your study doctor immediately if you make any changes to any of your current treatments, even those which you have been taking for a long time.

It is very important that your study doctor be informed very rapidly of any eventual changes to your health during your participation in the study. For your own security, it is important that you follow your study doctor's instructions throughout the entire duration of the study.

9. What kind of treatment will I receive after my participation in the trial?

No study product will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

10. What are the potential risks and side effects of being in this study? (compulsory)

Granisetron and acupuncture method both are known to be safe in pregnancy and widely used as antiemetic during pregnancy, have also been shown to be safe with low adversity when given as a single dose. Besides that, the study is aimed at improvement of postoperative patient comfort and is not administered for life saving or disease modifying purposes.

You might feel mild discomfort over the needle insertion site and minimal bleeding if vessel is accidentally punctured as the needle is really tiny. You may have skin irritation, blistering, redness and pain but usually is self-limiting.

The risks for subjects on both groups are nausea and vomiting but the risks will be managed by giving granisetron rescue doses or metochlopramide 10mg or both.

Please ask your study doctor if you need more information on risks and side effects.

11. What are the benefits of being in this study?

There may or may not be any benefits to you. Information obtained from this study will help to determine the ability of PC6 electroacupuncture in reducing the incidence of nausea and vomiting in patients who underwent spinal anesthesia where granisetron is used as single antiemetic.

12. What if I am injured during this study?

If you are injured as a result of being in this study, you should contact your study doctor. In the event of a bodily injury or illness directly resulting from the study product or a medical procedure required for this study, you will be treated in Hospital Raja Permaisuri Bainun until recover. The sponsor is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your study doctor or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

13. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get prophylaxis medication to prevent nausea vomiting as granisetron 1mg is the common practice to be given as antiemetic prophylaxis in caesarean section patient in Hospital Raja Permaisuri Bainun. Alternate treatments which are available are metoclopramide if you are allergy to granisetron. The study doctor will discuss in more details the benefits and risks of those treatments with you.

14. Who is funding the research?

This study is self-funding by investigators will pay for all study drugs and procedures. All other drugs and procedures that are not required by the study but are part of your routine medical care will have to be paid by you or your insurance.

15. Can the research or my participation be terminated early?

The study doctor or the sponsor may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed.

16. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

You will not be informed about the study outcome. You will be notified on any new information regarding the consent form.

Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

17. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor,

Dr Lee Chek Ning
MMC: 56159
contact number: 0125342845

or

Dr Chan See Yun
MMC: 39803
Contact number: 0125700148

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-33628407/ 8205/8888

INFORMED CONSENT FORM

Title of Study: PC6 electroacupuncture in the prevention of nausea vomiting in caesarean patient under spinal anesthesia

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study.

Subject:

Signature:

I/C number:

Name:

Date:

Investigator conducting informed consent:

Signature:

I/C number:

Name:

Date:

Impartial witness: (Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)

Signature:

I/C number:

Name:

Date: