

## OPTIONAL PARTICIPANT INFORMATION AND CONSENT FORM

**A Comparison OF EPIDURAL TECHNIQUES FOR LABOUR ANALGESIA**

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Neither the Principal Investigator nor the co-investigators have received financial compensation from any sponsor for the work required in doing this clinical research.

**1. INTRODUCTION**

You are being invited to participate in this study because you have asked for an epidural for pain relief during your labour. Receiving an epidural for labour pain involves using a needle to place a soft, plastic tube in your lower back that is used to inject medication close to your nerves to numb the pain from labour. At BC Women’s Hospital, anesthesiologists do epidurals using two techniques depending on their clinical preference: 1) standard epidural or 2) combined spinal-epidural (CSE) techniques.

Both methods are used routinely. We want to compare them to see if one technique may result in an overall lower amount of pain medicine used during labour. Using less medicine may mean fewer side effects.

# 2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate, you will be invited to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

**3.** **WHO IS CONDUCTING THE STUDY?**

The study is being conducted by the Department of Anesthesia at BC Women’s Hospital in Vancouver, British Columbia. The Principal Investigator is Dr Anton Chau and the study co-investigators are: Dr Jonathan Weale, Dr Vit Gunka and Ms Alison Dube. None of the study researchers have any conflict of interest to disclose.

# 4. BACKGROUND

Anesthesiologists usually give epidurals for labour using two common techniques: epidural or combined spinal epidural (CSE). In most cases, the technique used is chosen based on the preference of the anesthesiologist who places the epidural.

Epidural is the most commonly used technique as it is slightly simpler to do than CSE and may have fewer side effects than if intrathecal (spinal) medication is used in the CSE; in previous studies where a high dose of spinal medication was used there was an increased rate of maternal pruritis, uterine tachysystole and fetal bradycardia. In this study we will be performing the CSE without injecting spinal medications so we can avoid the side effects of intrathecal medications and compare the effectiveness of the different techniques rather than of the initial medication used. Compared with epidural, CSE without intrathecal medications may have faster onset of pain relief and allows confirmation of correct placement via the dural puncture. We are interested to see if the technique used affects how much medication is used over the course of labour*.*

# 5. WHAT IS THE PURPOSE OF THE STUDY?

This study is looking at the difference in the amount of medication required using an epidural that is placed using epidural or CSE techniques. This study will provide valuable information about minimizing the dose of medication needed to provide excellent pain relief during labour.

# 6. WHO CAN PARTICIPATE IN THE STUDY?

We would like to invite you to be part of the study if you are 19 years or older, are healthy, having a singleton pregnancy and are considering an epidural for pain relief.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

* Women who cannot have epidurals, or who have back problems, or have had back surgery that might affect the function of an epidural.
* Women who have a body mass index greater than 40, as this may make the procedures more difficult.

If you are unsure if you should be involved in the study, please ask the person discussing this consent with you.

# 8. WHAT DOES THE STUDY INVOLVE?

We aim to enroll 150 healthy women who request epidural for pain relief during their labour.

# Overview of the Study

Both the epidural and CSE procedures have already been shown to be safe and are already in use in this hospital. The care you receive will not be negatively affected in any way. In other words, your care may not be any different than if you were not in the study.

There will be three differences from standard practice if you choose to participate in the study. The proportion of epidural to CSE technique performed for labour pain is completely reliant on the anesthesiologist. In this study however, the technique used will be chosen at random; you will have an equal chance of receiving either an epidural or a CSE. Secondly, for this study, only staff anesthesiologists and senior research fellows will do the procedure. Lastly, we will only be injecting epidural medication and not adding spinal medication during the CSE procedure. Recent studies have shown that avoiding the addition of spinal medication may minimize side effects.

After the procedure your blood pressure, pain levels and the area of your body affected by the medication will be monitored closely, following the hospital’s standard procedure for epidurals.

# If You Decide to Join This Study: Specific Procedures

As stated above, you will be put in either the epidural or combined spinal/epidural group at random. To ensure that the results are fair between groups, only your Anesthesiologist will know which procedure you are having done. The procedure will be done in your room, exactly as normal for pain relief in labour.

In the epidural group, a hollow needle is used to place a soft plastic tube called an epidural catheter in the epidural space around your spinal cord. This tube can be used to inject pain medicine into the epidural space until delivery.

A CSE follows the same procedure, but before the epidural catheter is placed, a fine spinal needle is placed through the epidural needle making a microscopic hole in the dura layer (the layer between the epidural and spinal spaces) allowing epidural medicine to go into the spinal space as well. No spinal medications will be injected, so the pain relief will come from the epidural medication only, which is a change from usual practice. The spinal needle is then taken out and the rest of the procedure is identical.

After the procedure you will have the same monitoring as any woman with an epidural in labour. All study measurements are the usual measurements we take for all women receiving epidurals and will take place in your room. These will include regular blood pressure checks and checks of how much of your body is affected by the epidural (specifically, how much of your body is not reacting to cold sensation tested using an ice cube and how heavy your legs are). Data on your epidural will be taken from the epidural equipment after your delivery. You will usually be visited the day after you give birth to check how well your pain relief worked and to make sure it has worn off completely. However, all the information needed for the study is collected routinely, and if you feel well enough to go home before being seen we can collect the data from your chart.

If you decide not to join the study, your medical care will not change in any way. You will receive all the care that is normally provided at BC Women’s Hospital.

### **9. WHAT ARE MY RESPONSIBILITIES?**

You have no responsibilities during the study. You and your baby’s care will not be changed if you participate in this study other than as listed above. You will be involved in this study from the time of your baseline blood pressure measurement before your anesthesia until the delivery of your baby.

# 10. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

This study has no side effects above and beyond the normal risks of a normal epidural for pain relief. Many studies have shown that epidural and CSE are both safe in labour. Taking part in the study will not delay you getting your epidural.

**11. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

There are no direct benefits to you for being part of this study. We hope that the information we learn from this study may benefit women in the future by allowing us to reduce the amount of medications required to achieve pain relief in labour.

**12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?**

If you choose not to participate in this study the medical care that you will receive will not be affected in any way. This means 1) you will receive epidural placed either through epidural or CSE technique and the choice is determined by the anesthesiologist doing the placement and not randomly. 2) If a CSE technique is performed, you will receive medication in the spinal space. 3) All the checks for vital signs (e.g. blood pressure) and block spread (e.g. sensation to ice and heaviness in your legs) will still occur as they are usual practice, but they will not be used for this research study. You will receive all the care that is normally provided at BC Women’s Hospital.

**13. WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?**

If any new information comes to light that shows this study might affect your safety, or will not be helpful in making epidurals safer, we will contact you as soon as possible. You will still receive full, safe medical care.

**14. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?**

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let any of the research team members know.

15. HOW WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives ofthe UBC / Children’s and Women’s Health Centre of BC Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity (i.e. your name or any other information that could identify you) as a participant in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

**16. WHAT HAPPENS IF SOMETHING GOES WRONG?**

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

17. CAN I BE ASKED TO LEAVE THE STUDY?

If you are not able to follow the requirements of the study or if the study investigators feel that it is in your best interest for any other reason they may decide to withdraw you from or discontinue the study at any time and will arrange for your care to continue.

**18. AFTER THE STUDY IS FINISHED**

We believe that this study will take about 6 months to complete. If you are interested in knowing the results of the study, please contact the Department of Anesthesia at 604-875-2158 and one of the investigators will contact you.

**19. WHAT WILL THE STUDY COST ME?**

You will not incur any personal expenses as a result of participation in this study, nor will you be paid for participating.

**20.** **WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?**

If you have any questions or desire further information about this study before or during participation, you can contact Alison Dube (Research Assistant), Dr. Jonathan Weale (Co-investigator) or Dr. Anton Chau (Principal Investigator) at 604-875-2158. You can also reach the anesthesiologist on call at any time at 604-875-2161 (24-hour paging number). If you are interested in finding out the results of the study, you can contact the Department of Anesthesia at 604-875-2158.

21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT DURING THE STUDY?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

**A COMPARISON OF EPIDURAL TECHNIQUES FOR LABOUR ANALGESIA**

1. PARTICIPANT CONSENT TO PARTICIPATE

This consent form is not a contract. Signing this consent form in no way limits your legal rights, or those of your baby, against the study investigators or anyone else.

* *I have read and understood the participant information and consent form.*
* *I have had sufficient time to consider the information provided and to ask for advice if necessary.*
* *I have had the opportunity to ask questions and have had satisfactory responses to my questions.*
* *I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.*
* *I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.*
* *I understand that I am not waiving any of my legal rights as a result of signing this consent form.*
* *I have read this form and I freely consent to participate in this study.*
* *I have been told that I will receive a dated and signed copy of this form.*

# SIGNATURES

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Printed name of participant Signature Date

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Printed name of principal investigator/ Signature Date

designated representative