Quadratus Lumborum Block After Cesarean Section: Analgesic Efficacy of Different Concentrations of Local Anesthetics. A Randomized Clinical Trial

Unique Protocol ID: RP DAE/2022/102

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Consent Form for Participation in a Research Study

Title:
Quadratus lumborum block after cesarean section: analgesic efficacy of different concentrations of local anesthetics.

Principal Investigators:
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Introduction:
Caesarean delivery is the most common inpatient surgical procedure performed worldwide. Acute postpartum pain is a leading anaesthetic concern for women. Effective postoperative analgesia should, therefore, be prioritized to improve outcomes following caesarean delivery.
To apply the latest evidence-based practices towards improving maternal outcomes, Quadratus lumborum blocks have been studied in several obstetric randomized controlled trials, and postulate that it is associated with superior analgesic outcomes.

Background and Purpose:
QLB involves local anesthetic infiltration adjacent to the quadratus lumborum abdominal muscle, which may facilitate the spread of local anesthetic into the paravertebral space blocking both somatic nerves and the lower thoracic sympathetic trunk, the QLB could relieve both somatic and visceral pain, providing superior analgesia after caesarean section.
We designed a prospective randomized controlled trial to compare the analgesic efficacy of 2 different concentrations of local anesthetic (Bupivacaine) to standardize postoperative analgesic protocol used for QLB after caesarean section.

You have been asked to participate in this study because:
You have normal singleton pregnancy with a gestation of at least 37 weeks and you are scheduled for elective caesarean section under spinal anesthesia.

The purpose of this study is:
To compare the analgesic efficacy of 2 different concentrations of local anesthetic (Bupivacaine).

Study Visits and Procedures:
The participants in this study are the patients who are attending the pre-assessment anaesthetic clinic and are scheduled for elective caesarean section under spinal anesthesia.
Participants are randomly assigned into one of two groups; Group 1 to receive bilateral QLB with 0.125% bupivacaine 0.2 ml/kg, Group 2 to receive bilateral QLB with 0.25% bupivacaine 0.2 ml/kg.
All other anesthetic managements are performed in a standardized manner for all participants.

Alternatives to Participation:
Your participation in the study is voluntary. Your anesthesia and surgery management will go on as scheduled even if you do not participate in this study.

Risks Related to Being in the Study:
There are no medical risks if you take part in this study.

Benefits to Being in the Study:
You will not receive any medical benefit from your participation in the study. However, by participating you may help others by allowing better evaluation of this pain management.

Confidentiality:

If you agree to join this study, the study doctors will look at your personal health information and collect only the information they need for the study not including your personal information. All information collected during this study, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study. If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission

Questions:

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr. Jinan Jameel Al Aloosi, or Dr.Rabiah Noueihed through the hospital switchboard.

Consent:

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator	Signature	Date

Relationship to Participant	Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to and has had any questions answered.

Print Name of Witness	Signature	Date