PARTICIPANT INFORMATION SHEET TEMPLATE FOR ADULTS

Stavanger University Hospital
Stavanger Hospital Trust

Postoperative Pain After Caesarian Section

NCT number:

Date: 03 October 2022

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

WOULD YOU LIKE TO PARTICIPATE IN A RESEARCH PROJECT AND RECEIVE MORPHINE IN YOUR SPINAL ANAESTHESIA?

You are invited to participate in a research project where we will add a small dose of morphine in the spinal anaesthesia you will receive while undergo caesarean section. You have been asked to participate in this study because you are a woman planning a caesarean section.

WHAT IS THE PROJECT ABOUT?

Research and guidelines recommend to add Morphine in your spinal anaesthesia. Morphine will give you better postoperative analgesia the first 24 hours after your operation. It is also recommended to give you intravenous pain relief and prophylactic medicine for nausea (Paracetamol, Paracoxib and Dexametasone) while being operated. These medications will be given after the baby is delivered.

We will also do some changes with the medicine you will receive the first day after the operation. We will remove Oxycontin tablets, a long-acting opioid (works like morphine). We will also increase the dose of Ibuprofen.

If you participate in our study, we will follow you up more closely the first 24 hours. You will be asked questions about pain, nausea and itching- where you score using three different scoring tables. Nurses will document your answers every 30 min in the postoperative care unit and midwifes / nurses will document your answers every 4. hours in the maternity leave. Frequent observations are normal in the postoperative care unit, if you are participating in our project or not. In the maternity leave they will follow you up more frequent than normal. They will not wake you up in the night, you will be asked to call for them if you will need extra medicine for pain, nausea or itching.

We would like to change the procedures in our hospital following new guidelines. We would like to map how our patients are doing after receiving recommended treatment. We would like to map pain, nausea and itching the first 24 hours after receiving the spinal.

FORESEEABLE BENEFITS AND PREDICTABLE RISKS AND BURDENS OF TAKING PART

Advantages by participating in our project is that spinal morphine will give you better pain relief the first 24 hours after your operation. You will need less painkillers, this is also an advantage for the baby while nursing. Women mobilise better after the operation. Spinal morphine is safe for the mother and the baby.

Disadvantages is that morphine has side effects like nausea and itching. To reduce nausea, we will give you prophylactic medications. Itching, mostly located around eyes and nose, are well tolerated among most women. We have medication to relive the itch (Ondanserton and Naloxone) if needed.

VOLUNTARY PARTICIPATION AND THE POSSIBILITY TO WITHDRAW CONSENT

Participation in the project is voluntary. If you wish to take part, you will need to sign the declaration of consent on the last page. You can, at any given time and without reason withdraw your consent. This will not have any consequences for any future treatment

If you choose to participate in our project, you will receive morphine in your spinal anaesthesia. You will also receive prophylactic medications for pain and nausea under the operation. We will remove Oxycontin (morphine- like) tablets and increase Ibuprofen the first 24 hours.

If you choose not to participate, you will be given standard spinal anaesthesia without adding morphine. You will not be given prophylactic medicine for pain and nausea under the operation, you will of course be followed up closely and given extra medicine if needed. You will receive long-acting Oxycontin tablet after the operation and you will be given the same Ibuprofen dosage as we give today.

If you decide to withdraw participation in the project, you can demand that your personal data concerning health be deleted, unless however, the personal data concerning health and tests have already been analysed or used in scientific publications. If you at a later point, wish to withdraw consent or have questions regarding the project, you can contact section chief physician Jorunn Korneliussen, contact information at the bottom.

WHAT WILL HAPPEN TO YOUR PERSONAL DATA CONCERNING HEALTH?

Any personal data concerning health that has been recorded about you will only be used as described in the purpose of the project. You have the right to access information that has been recorded about you and the right to stipulate that any error(s) in the information that is recorded is/are corrected. You also have the right to know which security measures have been/will be taken when your personal data concerning health is processed.

All information will be processed and used without your name or personal identification number, or any other information that is directly identifiable to you. A code links you and your personal data concerning health via an identifier list. Only project manager Conrad Bjørshol and section chief physician Jorunn Korneliussen will have access to the information.

Information about you will be anonymised and planned to be used by 31.12. 22. For control purpose we will keep the information on an approved research server until 32.12.2027, after that they will be deleted.

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INSURANCE

Patient Injuries Act

FINANCE

Research group will receive payment form their employer. There are no sponsorship funds.

APPROVAL

The Regional Committee for Medical and Health Research Ethics has reviewed and approved the Research Project case number 194475

In accordance with the General Data Protection Regulation the controller Stavanger Universitetssykehus and the project manager Conrad Bjørshol is independently responsible to ensure that the processing of your personal data concerning health has a legal basis.

The processing of personal data is in accordance with REK (Regional ethical comitee) with case number 194475 and PVO (Data protection officer) at SUS ref. ID 1399.

You have the right to submit a complaint on the processing of your personal health data concerning health to the Norwegian Data Inspectorate (Datatilsynet).

CONTACT INFORMATION

If you have any questions regarding the research project, you can get in touch with

Jorunn Korneliussen, Section chief physician.

Mail address: korj@sus.no Mobile phone: 90470706

You can also get in touch with the Institution's Data Protection Officer (personvernombud) if you have any questions related to the use of your personal health data concerning health in the research project personvernombudet@sus.no.

I CONSENT TO PARTICIPATING IN THE RESEARCH PROJECT AND THAT MY PERSONAL DATA CONCERING HEALTH AND BIOLOGICAL MATERIAL CAN BE USED AS DESCRIBED ABOVE

[*Remove the alternative(s) that are not applicable*]

City/Town and date	Participant's Signature
	Participant's Name (in BLOCK LETTERS)

I confirm that I have given information about the research project [*You can include this sentence if you wish, only in the instances where the information is given face to face.*]

Place and date	Signature
	Role in the research project