05.09.2023

NCT05644873

NAME OF THE STUDY (EXPRESS NAME OF THE STUDY): Abdominal hysterectomy and bilateral Magnesium sulfate infusion in oophorectomy surgery perioperative Opioid consumption and its effect on postoperative analgesia

Volunteer's Initials << >>

You are asked to participate in a research study. Before deciding whether you want to participate, it is important that you understand why the study is being conducted, how your information will be used, what the study involves, its possible benefits, risks and any issues that may cause discomfort. Please take the time to read the information below carefully and, if you wish, discuss the matter with your private or family doctor. If you are taking part in another study, you cannot take part in this study.

DO I HAVE TO PARTICIPATE IN THIS STUDY?

The decision whether or not to participate in the study is entirely yours. If you decide to participate in the study, you will be given this Informed Consent Form to sign. If you decide to participate, you are free to leave the study at any time. This will not affect the standard of treatment you receive. If you wish, your physician/family doctor will be informed about your participation in this clinical trial. Additionally, if the supporting company decides to terminate the study, you will be removed from the study.

WHAT IS THE SUBJECT AND PURPOSE OF THE STUDY? Explain
abdominal hysterectomy and bilateral oophorectomy To observe the effects of painkillers routinely used during surgery on postoperative pain and to provide a comfortable postoperative period for these patients.

WORKING PROCEDURES:

In daily practice, as with any surgery, you will be given painkillers during and after your surgery. During the first 24 hours after the surgery, you will be visited by your anesthesiologist at routine intervals, and during this visit, questions such as your pain and complaints will be asked and blood pressure, pulse, and respiratory rate will be measured. Your surgery anesthesiologist will evaluate your post-operative comfort, satisfaction, whether you have pain, and if so, how long it lasts. will receive information about.

WHAT DO I NEED TO DO?
Each step to be applied within the scope of the study to be performed are procedures used in routine anesthesia practice. What you need to do is to trust your doctor and do exactly what he says. If you have a question or are unsure about something, do not hesitate to talk to your doctor about these issues.

WHAT POSSIBLE SIDE EFFECTS, RISKS AND DISCOMFORTS ARE THERE FROM PARTICIPATING IN THE STUDY?

Our study is a study that aims at patient comfort.
If there is anything that makes you uncomfortable, please inform your doctor.

PREGNANCY AND BIRTH CONTROL

Pregnant, breastfeeding women, children and elderly patients were excluded from the study.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY? (Explain if any)

Possible benefit of the study; The most effective method to prevent postoperative pain is abdominal hysterectomy and bilateral oophorectomy With its routine application in patients undergoing surgery, postoperative analgesic consumption will decrease and, accordingly, the undesirable side effects of analgesic drugs will be minimized .

VOLUNTARY PARTICIPATION

I make my decision to participate in this research completely voluntary. I am aware that I can refuse to participate in this study or leave at any time after participating, without the care and treatments I will receive in this treatment institution being affected and without taking any responsibility. If I leave the study at any time, I will discuss with my doctor the reasons for leaving, the consequences of my withdrawal, and any subsequent treatments I will receive.

WHAT IS THE COST OF PARTICIPATING IN THE STUDY?

Visits to the study doctor and all laboratory tests related to the study will be covered by the study sponsor and will not be reimbursed to you or your private insurance or government social security institution.

If any side effects or physical harm develop, immediately inform your study physician so that the necessary medical treatment can be administered.

HOW WILL MY PERSONAL INFORMATION BE USED?

By signing this form, you consent to your doctor and his/her staff collecting and using your personal information for the study (“Study Data”). This includes your date of birth, gender, ethnicity and your consent to the use of your study data does not have a specific date, but you can revoke your consent at any time by informing your doctor.

Study data shared with the study sponsor company will be protected through the use of a code (“Code”) number, which is a unique number for you. The code key required to access your study data is under the control of your study doctor. Persons appointed by the study sponsor company regulatory authority or other supervisory bodies may review your study data held by your doctor.

Your doctor will use your study data for the study.
The results of the study may be published in medical publications, but your identity will not be disclosed in these publications.

You have the right to ask your doctor for information about your collected study data. You also have the right to request correction of any errors in this data. If you have a request in this regard, please consult your doctor who can help you contact the study sponsor company if necessary.

If you withdraw your consent, your doctor will no longer be able to use or share your study data with others.
By signing this form, I consent to the use of your study data as described in this form.

PEOPLE WHO CAN BE REACHED 24 HOURS DURING THE RESEARCH:
Name:Principle
Surname: TAMDOĞAN
Phone:005062916678

SITUATIONS THAT MAY REQUIRE ME TO LEAVE THE WORK:

HOW NEW INFORMATION CAN AFFECT MY ROLE IN THE STUDY

Any new information that emerges while the work is in progress will be communicated to me immediately.

Consent to Participate in the Study

I have read all the explanations in the Informed Consent Form. Written and verbal explanations regarding the research whose subject and purpose were stated above were made to me by the physician named below. I know that I participated in the research voluntarily, that I can withdraw from the research at any time, with or without justification, and that I can be excluded from the research by the researcher regardless of my own will.
I agree to participate in the research in question with my own consent, without any pressure or coercion. My doctor has given me a copy of this document to keep, including the points I will pay attention to during the study.

Volunteer's Name / Surname / Signature / Date

Name / Surname / Signature / Date of the Person Making the Statements

Name / Surname / Signature / Date of the Person Who Witnessed the Approval Transaction, If Necessary

Name / Surname / Signature / Date of the Legal Representative, if necessary

* Explanations should be stated in a way that the participant can understand and should be free from technical terms.