Clinical study:

Comparative assessment of the efficacy of intraoperative infiltration anesthesia and femoral nerve block in primary knee joint replacement from clinical and functional perspectives. Prospective randomized study.

INFORMATION FOR THE PARTICIPANT

Dear patient,

You will undergo knee joint replacement surgery due to osteoarthritis. Currently, our clinic is conducting a study aimed at improving pain management protocols after knee joint replacement surgery. During the study, you will be randomly assigned to one of 4 study groups:

I – placebo

II – intraoperative infiltration anesthesia

III – femoral nerve block

IV – femoral nerve block and intraoperative infiltration anesthesia

Intraoperative infiltration anesthesia will consist of an injection of a mixture of pain-relieving medications. This mixture will be injected during the operation, during anesthesia, directly before implanting the prosthesis.

The femoral nerve block will involve injecting a local anesthetic solution in the vicinity of the femoral nerve. It is routinely used at SPSK im. prof. A. Grucy in Otwock.

The effectiveness and safety of both described above forms of pain management are supported by numerous studies and are used successfully in Poland and worldwide. In our Clinic, they will be performed by experienced medical specialists.

For research purposes, clinical data collected during the treatment process at the Department of Orthopaedics and Reumoortopedics CMKP will be used with due respect for your anonymity. Therefore, we ask for your consent to use data relating to your illness and treatment results for scientific purposes.

Before you decide, please read the attached information carefully and, if you have any doubts, discuss them with the persons responsible for the study. Please report any uncertainties; we are ready to provide any information related to the study topic. At every stage of the study there will be an opportunity to withdraw without giving a reason. Thank you for reading the document.

OBJECTIVE OF THE STUDY

The aim of the study is to compare the effectiveness of the two pain management methods used in knee joint replacement surgery in order to determine the therapy that yields the best results and maximally improves post-operative comfort after primary knee joint replacement. This may directly translate into rehabilitation outcomes and the final return to functional abilities.

QUESTIONS AND ANSWERS

What will happen to me if I participate in the study?

Each day of hospital stay, starting from the first day after surgery, you will be asked to rate your pain using a visual analogue scale. Apart from that, you are not obligated to perform any additional actions. No additional laboratory, imaging tests, or visits beyond the required hospital and outpatient care after surgery will be performed. If you consent to participate in the study, the supervising physician in consultation with the physician responsible for your treatment will enter information about your disease and test results into the research database, and will have access to information and tests during treatment.

Do I have to take part in the study?

Participation in the study is entirely voluntary, and at every stage you may withdraw without any consequences. If you consent to participate, you will receive this information sheet and will be asked to sign a written consent. A decision to withdraw from the study at any time or not to enter the study will not affect the standards of medical care thereafter. If you request withdrawal during the study, we will ask you for consent to retain at least the data collected up to that point, but of course all your wishes in this regard will be respected.

Will my participation in the study be kept confidential?

All information collected during the study will be treated as strictly confidential, and of course any personal data enabling your identification will be omitted in the results. Your treating physician will be informed about your participation in the study until you express a desire to withdraw.

What kind of data will be collected?

Age, sex, body weight, height, BMI, deformity degree and joint mobility before and after surgery, pain intensity scale 1-5 on the postoperative day 1, CRP concentration results on postoperative days 3 and 5, amount and type of analgesics used and duration of administration

How long will my data be stored?

We will ask you for permission to store your anonymous data in accordance with regulations on the retention of patient records after planned operations.

Will participation in the project bring me any direct benefits?

This project aims to improve the quality of pain management for patients undergoing knee joint replacement, so the potential benefit of participation is a reduction in postoperative pain.

What are the possible harms and risks of participating in the project?

There is a possibility of previously undiagnosed allergic reactions to the medications used, but this risk is no higher than with the use of any other medications during hospitalization. In addition, to the best of our knowledge, the proposed pain management methods do not involve a significant increased risk of complications.

What will happen to the results of the project?

The results will be published in medical specialist literature. Your personal data will not be disclosed in any publication.

Who is organizing and funding the study?

The Department of Orthopaedics and Reumoortopedics, CMKP (Central Medical Postgraduate Education Medical Center) in Warsaw, located at the SPSK im. Prof. A. Grucy in Otwock. Direct supervision of the research project will be by Prof. Dr. Hab. Med. Jacek Kowalczewski and Dr. Hab. Med. Dariusz Grzelecki.

In addition, we inform you that:

Your data will not be used for commercial purposes

The discussed research project has been presented to an independent bioethics committee and positively approved before the research commenced.

Contact for further information

People from whom you can obtain more information include:

The physician caring for you directly or

Dr. Maciej Kocon, Prof. Dr. Hab. Med. Jacek Kowalczewski, Dr. Med. Dariusz Grzelecki

Department of Orthopaedics and Reumoortopedics, CMKP

SPSK im. Prof. A. Grucy in Otwock.

I have read the information regarding the above-mentioned study, and I have been given complete answers to all my questions and concerns.

DATE	NAME AND SURNAME	PATIENT'S SIGNATURE
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