REQUEST FOR PARTICIPATION IN THE RESEARCH PROJECT

ANTIBIOTIC-LOADED BONE CEMENT IN PREVENTION OF PERIPROSTHETIC JOINT INFECTIONS IN PRIMARY TOTAL KNEE ARTHROPLASTY: A REGISTER-BASED MULTICENTER RANDOMIZED CONTROLLED TRIAL (ALBA TRIAL)

This is an invitation for you to participate in a research project aiming to compare cemented total knee prostheses with or without antibiotics in the bone cement.

You are scheduled for a knee replacement surgery. Knee prosthesis is an established treatment with good results for most patients. The surgery involves inserting an artificial knee joint made of plastic and metal, which is attached to the bone using bone cement. One of the most common reasons for reoperation following primary knee arthroplasty is infection.

The infection-preventing effect of antibiotics in bone cement for primary total knee replacement is insufficiently documented. In most European countries, including Norway, antibiotics are routinely used in bone cement, in contrast to the USA, where antibiotics in bone cement are not approved for use in standard knee replacement surgery. It would be unfortunate to use antibiotics in the cement if it does not prevent infections, as unnecessary antibiotics use can lead to an increase in resistant bacteria. This study aims to determine whether antibiotics in bone cement reduce the incidence of infection after knee replacement surgery. Patients undergoing total knee replacement surgery at all hospitals in Norway will be included, and it will be randomly decided whether you will receive bone cement with or without antibiotics. We will also investigate which method results in less morbidity, complications, and reoperations. Quality of life, pain, function, and patient satisfaction will also be assessed.

If you do not wish to participate in the study, the surgeon will decide whether you will receive bone cement with or without antibiotics. Whether you participate in the study or not, you will still receive standard antibiotics in your bloodstream during surgery according to national guidelines.

WHAT DOES PARTICIPATION IN THE STUDY INVOLVE?

The study involves no extra burden for you. Just before the operation, the surgeon will use computer-generated randomization to decide whether you will receive antibiotics in the cement or not. You will follow routine post-operative care at your hospital. To participate in this study, you must provide written consent to be registered in the Norwegian Arthroplasty Register and to participate in this study.

DATA HANDLING AND PRIVACY

Participation is voluntary, and you can withdraw from the study at any time, even after the surgery. If you choose not to participate in the study, this will not affect your treatment at the hospital, and you will undergo surgery according to standard hospital procedures.

The data collected will be stored and processed at the Norwegian Arthroplasty Register. This includes information such as your national identification number, diagnosis, reason for surgery, medication use, and surgical details. The same information will be collected if you need to undergo reoperation surgery on the same knee, and bacterial samples will be collected

during the new surgery.

You will be asked to fill out a questionnaire about your self-assessed quality of life and joint function before the surgery. We will also ask for information about your height, weight, activity level, education level, alcohol use, and whether you smoke. We will ask for permission to contact you again to fill out a similar evaluation at 1, 6, and 10 years after the primary surgery.

The study is a collaborative project between all Norwegian hospitals that perform knee replacement surgeries. All information will be treated confidentially. The project will conclude in 2034, after at least 10 years of follow-up for all patients. The data will be retained in the Norwegian Arthroplasty Register as long as necessary approvals are in place.

The information collected about you will be stored electronically and will only be used as described in this document. All data is protected against unauthorized access. Directly identifiable information, including your name, national identification number, or other personal identifiers, will be stored separately from the other data on a secure research server at Helse Bergen. A code links you to your information through a name list. Only the project leader and the head of the Norwegian Arthroplasty Register have access to the name list and can trace your information. Results from the study will be presented at conferences and published in national and international medical journals. Results based on analyses from the study cannot be traced back to individual participants.

POSSIBLE BENEFITS AND RISKS

There is a theoretical possibility that patients randomized to receive cement without antibiotics may have a higher risk of prosthesis infection. However, the risk is still very low (about 1.5%). We do not know this for sure yet. On the other hand, patients who receive antibiotics in the cement may have a risk of developing antibiotic-resistant bacteria, allergic reactions, and side effects from the antibiotics in the cement.

VOLUNTARY PARTICIPATON AND WITHDRAWAL OF CONSENT

Participation in the project is voluntary. If you wish to participate, please sign the request to participate in the Norwegian Arthroplasty Register. You can withdraw your consent at any time without giving a reason. This will not affect your further treatment. If you withdraw from the study project, you can request to have the collected information deleted. If you later wish to withdraw, you can contact the Norwegian Arthroplasty Register, Helse Bergen HF, Department of Orthopedics, Haukeland University Hospital, Møllendalsbakken 7, 5021 Bergen. Phone 55 97 37 42 / 55 97 37 43 or e-mail nrl@helse-bergen.no.

WHAT HAPPENS TO THE DATA COLLECTED ABOUT YOU?

Your data will be registered in the Norwegian Arthroplasty Register.

APPROVAL

The Regional Committee for Medical and Health Research Ethics has reviewed the project and given prior approval: 2019/751/REK vest.
Under the new data protection law, the Director of Helse Bergen is responsible for ensuring that your data is processed on a legal basis.

This project is legally based on the EU General Data Protection Regulation, Article 6(1)(e) ("task in the public interest") and Article 9(2)(j) ("research"), together with provisions in the Health Research Act as the legal basis for data processing.
You have the right to complain about the processing of your data to the Data Protection Authority.

CONTACT INFORMATION

If you have any questions regarding the study, you can contact your treating physician or the Norwegian Arthroplasty Register, Helse Bergen HF, Department of Orthopedics, Haukeland University Hospital, Møllendalsbakken 7, 5021 Bergen. Phone 55 97 37 42 / 55 97 37 43 or e-mail nrl@helse-bergen.no. The study project is led by Researcher/nurse/associate professor Tesfaye H. Leta at the Department of Orthopedics, Haukeland University Hospital.

Best regards,

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INFORMED CONSENT

I have read the attached information and discussed the study with the responsible physician. I am willing to participate in the study.

Patient's signature Date: