Diakonhjemmet Sykehus

MERINO:2
Methotrexate in erosive inflammatory osteoarthritis

# **MERINO:2** | AN ADDITIONAL FOLLOW-UP OF PARTICIPANTS IN THE MERINO STUDY

## PURPOSE OF THE PROJECT AND WHY YOU ARE BEING ASKED

You are invited to participate in a follow-up study after the MERINO study at Diakonhjemmet Hospital. We would like to take an X-ray of your hands and ask you to complete some questionnaires at home regarding your osteoarthritis symptoms.

The aim is to compare the long-term effects of methotrexate with treatment as usual. No other studies have examined the long-term effects of methotrexate. Therefore, we are inviting all participants from the MERINO study to an additional follow-up 2.5 years after enrollment in MERINO. We will compare this with the initial data collection from the MERINO study, and this request goes to all who were recruited to the MERINO study, regardless of whether they completed it or not.

The study is conducted by the Department of Rheumatology at Diakonhjemmet Hospital and led by Alexander Mathiessen.

**Status of the original MERINO study:** As of October 2024, 131 of 153 participants have been recruited and we hope to complete recruitment by February 2025. The main analysis is planned once all participants have completed 6 months of treatment.

## WHAT DOES THE PROJECT INVOLVE FOR YOU?

If you agree to participate, you will:

1. Be invited for a hand X-ray approximately 2.5 years after recruitment to the MERINO study.
2. Receive a link to complete some online questionnaires (via Nettskjema), which you can answer at home using a mobile phone or computer with secure BankID login.

We will compare your answers with data from the original study and collect information about your medication use during this period from the Norwegian Prescription Database.

## POSSIBLE BENEFITS AND DISADVANTAGES

MERINO:2 requires your time for an X-ray appointment and completion of questionnaires.
Those living near Oslo will have their X-ray taken at Diakonhjemmet Hospital. Those living farther away will be invited to a radiology clinic near their residence.

Hand X-rays involve minimal radiation, equivalent to approximately 3 hours of natural background radiation.

The questionnaires take approximately 15 minutes to complete.

There are no direct personal benefits, but the results will provide valuable additional data at the group level.

## VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW CONSENT

Participation in the project is voluntary. If you wish to participate, you sign the consent form. You may withdraw your consent at any time without providing a reason. This will not have any negative consequences

for you or your treatment. If you withdraw your consent, your data will no longer be used in research. You may request access to your data, which will be provided within 30 days. You can also request that your data be deleted from the project.

The right to request deletion or access does not apply to anonymized or published data. It may also be limited if the data have already been included in completed analyses.

If you later wish to withdraw or have questions about the project, you can contact the project leader (see contact information on the last page).

## WHAT HAPPENS TO YOUR DATA?

Your personal data will only be used as described in the project's purpose. After the study is completed, your data will be stored for five years for auditing purposes. Any extension of use and storage must be approved by the Regional Committees for Medical and Health Research Ethics (REK) and other relevant authorities.

You have the right to access and correct any of your registered personal data. You also have the right to learn about the security measures used in data processing. You may file a complaint about data processing with the Norwegian Data Protection Authority or the institution's Data Protection Officer.

All data will be handled without name, national ID number, or other direct identifiers (= coded data). A code will link you to your data through a name list. This list will be kept at Diakonhjemmet Hospital and only accessible to study personnel.

Publishing the study's results is part of the research process and will be done using grouped data, making it impossible to identify individuals.

## DATA SHARING AND TRANSFER TO COUNTRIES OUTSIDE NORWAY

As part of the study, data may be transferred to international collaborators, both within and outside the EU/EEA (e.g., the UK and the USA). In such cases, the data (questionnaires and X-rays) will be de-identified, and used only for the research purposes described in this consent form. Diakonhjemmet Hospital is responsible for ensuring the transfer complies with Norwegian and EU privacy laws (GDPR). The code that links your data to your identity will not be shared. Information about such collaborations and data transfers will be available as they occur at: www.remedy-senter.no/project/merino.

## INSURANCE

You are covered by the Norwegian Patient Injury Compensation Scheme (Patient Injury Act).

## FINANCES

There is no cost to you for participating. All expenses are covered by the sponsor, Diakonhjemmet Hospital. Travel expenses will be reimbursed.

## APPROVALS

The Regional Committee for Medical and Health Research Ethics (REK) has ethically reviewed and approved the project (REK 2024/715758).

Under the new Personal Data Act, Diakonhjemmet Hospital is the data controller for your personal data. Project leader Alexander Mathiessen has an independent responsibility to ensure lawful processing. This project is based on your consent and legal grounds provided by Articles 6(a) and 9(2)(a) of the GDPR. You have the right to complain to the Data Protection Authority.

## CONTACT INFORMATION

If you have questions about the project, experience any unwanted events or side effects, or wish to withdraw from participation, please contact project leader Alexander Mathiessen:
Phone: +47 975 01 889
Email: a-mathi1@diakonsyk.no

If you have questions about data privacy, you may contact the Data Protection Officer at the institution:
personvern@diakonsyk.no

## I CONSENT TO PARTICIPATE IN THE PROJECT AND FOR MY PERSONAL DATA TO BE USED AS DESCRIBED ABOVE.

| | |
|---|---|
| Place and date | Participant's signature |
| | Participant's name (printed) |