Would you like to participate in the research project «Artificial intelligence in BreastScreen Norway – a randomized controlled trial»?

This is an invitation for you to participate in the research project «Artificial intelligence in BreastScreen Norway – a randomized controlled trial», also called "AIMS Norway" (Artificial Intelligence in Mammography Screening in Norway). The study will test and evaluate a new procedure for assessing mammograms in BreastScreen Norway. The procedure will include use of artificial intelligence. In this context "artificial intelligence" means a computer program that recognizes specific patterns in mammograms which can indicate breast cancer as it has been trained to do so by analyzing a large number of mammograms over many years.

This type of artificial intelligence can assist radiologists in evaluating mammograms. The computer program tested in this study is CE marked. This means the product meets the safety requirements that the EU has set for medical equipment. The Cancer Registry of Norway is the responsible research institution, and the study has been approved by the Regional Committee for Medical and Health Research Ethics (#366405).

Why we want to include you in the study

You are invited to participate in this study because you have been invited to BreastScreen Norway. Your participation enables us to investigate whether artificial intelligence in combination with radiologists is as good as or better at detecting breast cancer than the current standard procedure, where two radiologists evaluate all mammograms independently. This could mean a significant reduction in the need for radiologists in BreastScreen Norway, without reducing the quality of the program.

What does participation imply for you?

Participation in the study means you will be randomly placed in a **study** or **control group**. You cannot influence which group you are placed in.

If you are in the **study group**, your mammograms will be assessed by the computer program in addition to one or two radiologists, depending on the computer program's assessment of your images. Mammograms that the computer program classifies as having a low risk of breast cancer will be evaluated by one radiologist, while examinations classified as intermediate to high risk will be evaluated by two radiologists (standard procedure).

If you are in the **control group**, your mammograms will be evaluated by two radiologists, following standard procedure. The computer program will assess the images, but the result will not affect the evaluation done by the radiologists, only be used in later analyses.

As usual in BreastScreen Norway, at least two radiologists will always discuss your images in the event of suspected findings and decide whether additional examinations are needed. **Your attendance and screening examination, as well as any follow-up or treatment, will be performed as usual, regardless of whether you participate in the study or not, and in which group you are placed.**

Advantages and disadvantages

Participation will have no direct advantages or disadvantages for you. By participating, you will contribute to increased knowledge that can help us decide whether artificial intelligence should be included in the standard procedure for evaluating mammograms, and thereby contribute to a more cost-effective program. The computer program could detect changes and tumors that are difficult for the radiologists to detect. In general, early detection of breast cancer can lead to less aggressive treatment, better quality of life and fewer women dying from the disease compared to detection of symptomatic cancer.

The computer program could also suspect breast cancer more often than the radiologists. This increases the risk of being recalled for additional examinations, without detecting breast cancer. These "false alarms"

could cause unrest and anxiety. The computer program also runs the risk of missing signs of breast cancer. Risk of false alarms and overlooked breast cancer is also present with ordinary participation in the program. To reduce the risk of possible disadvantages, at least one radiologist will evaluate the mammograms in addition to the computer program. The study will be closely monitored throughout the study period to ensure the safety of the participants. In the event of deviating results, immediate measures will be taken.

What happens to your information?

Data from your mammograms will be sent to the computer program for analysis. All directly identifiable data are removed from the images before they are sent to the computer program (pseudonymization). The computer program uses a cloud-based service that makes use of data centers located in the EU or EEA. Directly identifiable data will only be stored within the hospital's network and will not be sent out of Norway. Data sent to the cloud service is only stored temporarily, and using this will not affect your rights to deletion of or access to the information stored about you in the study.

We will register and use the information given by the computer program. This includes a score indicating the likelihood of breast cancer. In addition, we will use information related to your attendance in BreastScreen Norway and possible mammographic findings, stored in databases at the Cancer Register of Norway. We will also use the mammograms, stored in your patient record, to do quality assessment of the study results. Only authorized personnel, who are subject to a duty of confidentiality, will have access to identifiable information about you.

This information will be used to monitor the study throughout the study period, as well as for analyses. The results will be made public and published in scientific journals. When analyzing the study results, names, personal identification numbers and other directly identifiable information will be deleted. All results will be anonymized, and it will not be possible to recognize you in any published works. The planned study period is 2023-2033. Information will be stored for five years after study completion, for documentational purposes. Any extensions in the use and storage of study information occurs only after approval from the Regional Committee for Medical and Health Research Ethics and if the processing has legal basis. If all permissions are in place, information can be made available to collaborating research institutions and linked to other health registers and sources, including Statistics Norway and the Norwegian Patient Registry. Use of information will be limited to purposes coinciding with the project purpose.

Voluntary participation

When you attend your screening invitation, you will be asked if you are willing to take part in the study. **If you agree to having your mammograms and related information about you included in the AIMS study as described above, you will be asked to give your consent before your screening examination.** Your signed consent gives the study legal basis according to the General Data Protection Regulation (Article 6 (1)(a), and Article 9 (2)(a)) to process your personal data. If you do not want to participate, your mammograms will not be assessed by the computer program.

You can, without giving any reason, withdraw your consent at a later stage using the contact information provided below. If you choose to withdraw your consent after the computer program has assessed your images, we will delete all information about you related to the study. There will be no consequences for you, any possible follow-up, or future invitations to BreastScreen Norway. You can demand access to the information registered about you and get insight into how the information is processed and who has had access to this information.

Contact information

If you have any questions about the study, contact the Cancer Registry of Norway and project manager Solveig Hofvind by telephone +4722928828 or e-mail sshh@kreftregisteret.no. Data protection officer for the institution is Kjersti Haugan. General questions and inquiries about privacy can be sent to personvernombud@fhi.no. More information about the study: kreftregisteret.no/en/AIMS-Norway.