Would you like to participate?

Breast cancer screening with a contrast mammogram for women with very dense breast tissue.

Comprehensive information brochure

Website: www.dense-2.nl

Why this study?

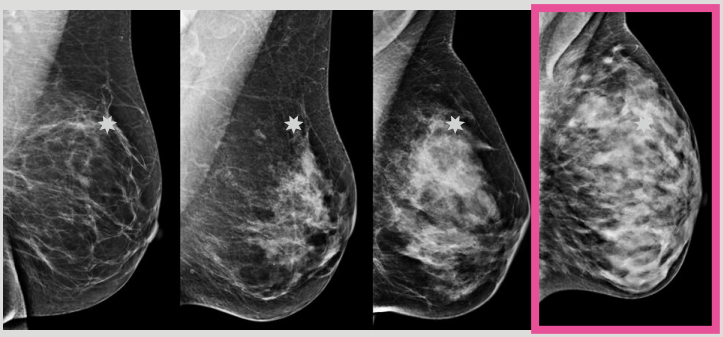
Your latest mammograms show no evidence of breast cancer. Your latest mammograms do show that you have very dense breast tissue. This is important for two reasons:

1. Women with very dense breast tissue are more likely to develop breast cancer than those with less dense breast tissue.
2. Very dense breast tissue can hide breast cancer on a mammogram. This makes it harder to tell if you have breast cancer.

Women with very dense breast tissue therefore benefit from other ways of breast imaging. **In the DENSE-2 study, we will explore different ways. You have been invited for a contrast mammogram.**

What is very dense breast tissue?

A breast consists of glands and fat. Women with very dense breast tissue have many glands in the breast and little fat. Glands appear white on a mammogram, just as breast cancer does. It is therefore difficult to actually see the breast cancer. The star in the four mammograms below shows this: in the rightmost mammogram, the star is harder to see.

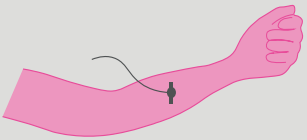


Less dense breast tissue — Very dense breast tissue

What is a contrast mammogram?

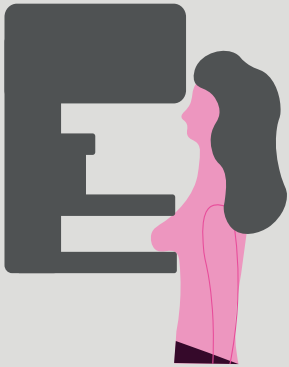
A contrast mammogram is made using the same device as a mammogram. The difference with a regular mammogram is that contrast medium is given beforehand. This is done through an IV into a blood vessel in your arm. The contrast medium may cause you to experience a foul taste in your mouth. You may also feel a warm sensation throughout your body and feel like you are peeing your trousers. This is not really the case, it only feels that way. This feeling dissipates after a few minutes. If you have breast cancer, the contrast medium will make it easier to see. You will excrete the contrast medium through your urine.

1



You will receive contrast medium through an IV in your arm.

2



A mammogram is made in the same way as in the population screening.

What are the benefits of participating in this study?

- The chances of finding breast cancer are higher with a contrast mammogram than with a mammogram.
- You contribute to improvements in the breast cancer population screening.

What are the disadvantages of participating in this study?

- You may experience an adverse reaction to the contrast mammogram (see below).
- With a contrast mammogram, false positives are slightly more common than with a regular mammogram. More hospital tests are then required, when in retrospect they were not necessary.

Is a contrast mammogram safe?

- **Radiation.** A contrast mammogram requires a bit more radiation than a mammogram. You also receive radiation in everyday life. We use as little radiation as possible with each mammogram. The amount of radiation is well within the limit for the population screening. Radiation can cause cancer, but that risk is minimal at this amount.
- **Kidney function.** If you have very poor kidney function, the contrast medium (iopromide) pose risks to your health. We will determine during a call with you whether your kidney function needs to be measured. If necessary, blood will be drawn just before the contrast mammogram. The lab technician will immediately know whether or not you can participate in the study. This is done during your contrast mammogram appointment; you do not have to make an extra hospital appointment.
- **Side effects.** A small proportion of people who receive a contrast mammogram experience an adverse reaction to the contrast medium. These side effects are usually mild. Serious side effects are very rare. The website lists all possible side effects: link website

The most common **side effects** are:

- Headache
- Nausea
- Temporary dilation of blood vessels, you may experience light-headedness

What can you expect if you participate?
The study in 7 steps

1) The invitation. You have received this information brochure, a brief leaflet, a letter from Bevolkingsonderzoek Nederland, a questionnaire and the consent form. **Participation in this study is voluntary.**

2) The registration.

- You do not have to decide right away whether you really want to participate in the study. You can discuss this with a member of the study team first, for which you can make an appointment. You can do this through the website: www.dense-2.nl. You can use your details from the letter from Bevolkingsonderzoek Nederland to log in. Having problems logging in? The study team can best assist you if you send an email to: dense-2@umcutrecht.nl. If you are unable to email, you can call 088-7553075.
- Once you have registered, we will call you to discuss whether you are able and willing to participate in the study.
- During the phone call, we will go through the questionnaire you received together with this brochure. Please complete this questionnaire **before** we call you.
- You fill in the form in order to give consent. You will receive further explanation about this during the phone call.
- You schedule an appointment for a contrast mammogram at a hospital in your area. You will receive further explanation about this during the phone call.

3) Questionnaire. After your registration, but before the contrast mammogram, you will receive another questionnaire. We ask you to complete this questionnaire at home. We would like to understand what determines why women have very dense breast tissue. Completing the questionnaire takes about 15 minutes.

4) A contrast-mammogram

You will be in the hospital for approximately 30 minutes.

- The lab technician will insert an IV into your arm.
- During the phone call in step 2 (the registration), it was decided whether your kidney function should be measured. If necessary, some blood will be drawn from the IV in your arm. This is done during your contrast mammogram appointment. The lab technician taking the contrast mammogram will immediately know whether or not you can participate in the study.
- You will be given contrast medium.
- A mammogram is taken, in the same way as in the population screening.

5) The result. A radiologist at the hospital reviews the contrast mammogram. You will receive the results within two weeks. If further examination is needed at the hospital, you will be called by the DENSE-2 studyteam. Your GP will then also be informed.

6) Questionnaire. After the contrast mammogram, you will receive a questionnaire. We would like to ask you to fill it out at home. We would like to know how you experienced your participation in the study. Completing the questionnaire takes about 15 minutes in total.

7) Two rounds of a contrast mammogram.

If you decide to participate in the DENSE-2 study:

- You will undergo a contrast mammogram
- After that, you will simply be invited again for the next round of breast cancer population screening.
- You will participate in the breast cancer population screening again and have mammograms taken.
- If your mammograms again show no evidence of breast cancer, we will invite you for a second contrast mammogram. You will then also receive the same questionnaires you received in step 1 and step 3.
- After the second contrast mammogram, you will receive one more questionnaire. This is the same questionnaire you received in step 6. After that, your contribution to the DENSE-2 study is complete.

You can stop participating in the DENSE-2 study at any time.

What does it cost?

Participation in this study is free of charge, meaning you do not have to pay anything for the contrast mammogram. You will also receive a €25 gift voucher as a concession for travelling to the hospital. However, it may happen that an abnormality in the breast is found. Follow-up hospital tests are then required. **The cost of this is covered by your healthcare insurance.** It may be that you have to pay all or part of these costs yourself. This depends on how high your deductible is and how much of it you have used up. Do you have any questions about this? If so, contact your healthcare insurer.

What do we do with your data?

If you participate in the study, all your personal and study data will be kept confidential. Your personal data will be replaced by a code in the study documents. This code is kept separately from your data. Only the researchers will have access to your data as part of this study. Staff of the 'Health and Youth Care Inspectorate' and the Health Council of the Netherlands can use it to check the safety and quality of the study.

If the contrast mammogram finds anything that could be breast cancer, tissue is usually removed. This is then viewed under the microscope. Some of this tissue is often left over. This is called 'residual material'. We kindly request you to allow us to use this residual material for future research. If you do not want this, please indicate this on the consent form.

How long will your data be kept?

Your data is guarded under the 'General Data Protection Regulation' (GDPR/AVG). All data will be kept for 20 years. We ask your consent to be allowed to include this data in the form of a code in a public database. We also ask for your consent to use the data for future breast cancer studies. Studies may involve new research questions even after the study has officially ended. It is sometimes possible to answer the new questions using the information collected in previous studies.

I do not want to participate in the study.

If you do not wish to participate in the study, we would like to ask you to let us know via the website: www.dense-2.nl. We will then no longer contact you for this study. I**f you do not want to participate in the study, it will not affect your possible treatment or counselling in the future.** It is also good to know that the study will not affect your participation in the breast cancer population screening. You will simply be invited again for the next round of breast cancer population screening.

Can you stop participating in the study?

You can stop participating in the DENSE-2 study at any time. Please inform the researchers as soon as possible. You can do this via the link in the confirmation email you received when you signed the consent form. You can also do this via the form on the website, or by calling the study team. You do not need to explain why you want to stop. In case you stop participating in the study, the researchers will use the data collected up to the point of your withdrawal for the study.

Partners DENSE-2 study

albert schweitzer
Amsterdam UMC
ANTONI VAN LEEUWENHOEK NEDERLANDS KANKER INSTITUUT
bevolkingsonderzoek nederland
borstkanker vereniging
catharina een santeon ziekenhuis
Erasmus MC Universitair Medisch Centrum Rotterdam
etz
Jeroen Bosch Ziekenhuis
Maastricht UMC+
Radboudumc
Rijnstate
ST ANTONIUS een santeon ziekenhuis
umcg
UMC Utrecht
zgt
Zuyderland De zorg van je leven

Other information

The Minister of Health, Welfare and Sport assessed this study under the Population Screening Act (Wet op het bevolkingsonderzoek, or WBO) and granted a licence to conduct this study from July 1st 2024 to September 31st 2031.

This study is conducted from UMC Utrecht.

This study is funded by: ZonMw, Hologic, Siemens Healthineers, Bayer

More information?

- More information about this study can be found on our website: www.dense-2.nl.
- Questions? Call the study team: 088-7553075 or send an email: dense-2@umcutrecht.nl.
- If you require independent advice on this study, please contact Desirée van den Bongard, via email: h.j.vandenbongard@amsterdamumc.nl or via phone number: 020-4441571.
- General information about participating in medical-scientific research can be found on the central government website (topic 'Medical-scientific research').
- Want to know more about your privacy? Then visit the website of the Personal Data Authority (www.autoriteitpersoonsgegevens.nl) or contact the Data Protection Officer at UMC Utrecht (privacy@umcutrecht.nl).
- Do you have a complaint? If so, discuss this with the study team. If you would prefer not to, then please approach the Complaints Mediation Department of UMC Utrecht at https://www.umcutrecht.nl/nl/een-klacht-indienen or by calling 088 75 562 08.

More information?

Please visit our website: www.dense-2.nl