



Would you like to participate?

Breast cancer screening with an MRI examination for women with very dense breast tissue.

Comprehensive information brochure

Website: www.dense-2.nl

Why this study?

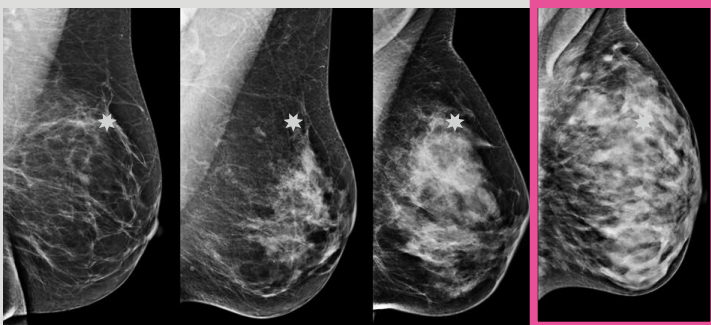
Your latest mammograms show no evidence of breast cancer. Your latest mammograms do show that you have very dense breast tissue. This is important for two reasons:

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 an MRI examination.**

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.



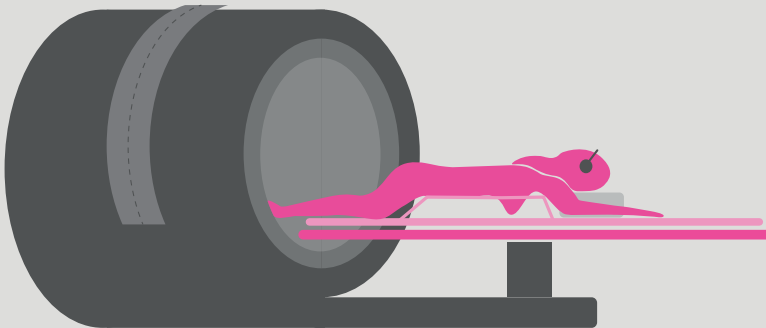
Less dense breast tissue

Very dense breast tissue

What is an MRI examination?

During the MRI examination, you lie on a bed in a kind of tube. Your breasts hang down during this process. The tube is illuminated and is open at the front and back. You will lie in the MRI scanner for about 5 minutes. The MRI machine makes quite a bit of noise. You will be given headphones for this reason and, if you wish, music will be played. The lab technician is in another room during the examination. From this room, the lab technician can see you. An intercom always ensures contact between you and the lab technician. During the MRI examination, you will be injected with a contrast medium (gadolinium). This is done through an IV into a blood vessel in your arm. If you have breast cancer, the contrast medium will make it easier to see. Most people notice little or nothing from the contrast medium. After the examination, the IV is removed from your arm. You will excrete the contrast medium through your urine.

The MRI device. You will be moved into the MRI scanner during the MRI examination. You lie on your stomach in the MRI scanner.



What are the benefits of participating in this study?

- The chances of finding breast cancer are higher with an MRI examination than with a mammogram alone.
- 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 MRI examination (see below).
- With an MRI examination, false positives are slightly more common than with a mammogram. More hospital tests are then required, when in retrospect they were not necessary.
- There is a very small chance of finding an abnormality outside the breast by chance (see page 9).

Is een MRI-onderzoek veilig?

An MRI examination is safe, but there are some minor risks:

- **Metal.** If you have metal objects in your body, you may not be allowed in the MRI scanner. This depends on the type of metal and its location in the body. Usually, you can also enter the MRI scanner safely with metal objects. The researchers determine this with a questionnaire.
- **Contrast medium.** It has been shown that very small amounts of contrast medium can be absorbed into the body, including in brain tissue, bones or skin. For 40 years, millions of people have been receiving contrast-enhanced MRI examinations. No adverse health effects of this are known.
- **Side effects.** A small proportion of those who undergo an MRI examination experience an adverse reaction. These side effects are usually mild. Serious side effects are very rare. The website features an overview of all possible side effects: www.dense-2.nl.

The most common **side effects** are:

These side effects occur in about 5 in 1,000 people.

- Headache
- Nausea
- Dizziness

Other **experiences** that sometimes occur are:

- Due to the small space, you may be anxious during the examination. If you suffer from (severe) claustrophobia you cannot participate in this study. You can ask your GP for a sedative if you still want to participate.
- Some people do not like lying on their stomach or the sound of the MRI scanner.

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. Do you have 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 an MRI examination 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 MRI examination, 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) The MRI examination.



You will be in the hospital for approximately 30 minutes.

- The lab technician will insert an IV into your arm.
- You will lie on your stomach in the MRI scanner.
- You will lie in the MRI scanner for about 5 minutes.

5) The result. A radiologist at the hospital reviews the MRI. 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 MRI examination, 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 MRI.

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

- You will have an MRI examination.
- 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 MRI examination. You will then also receive the same questionnaires you received in step 1 and step 3.
- After the second MRI examination, you will receive one more questionnaire. This is the same questionnaire you received in step 1.
- 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 MRI examination. 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 MRI examination 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. If 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.

What happens when something unexpected is discovered?

The MRI image shows other organs and tissues besides the breasts. This means there is a small chance of finding an abnormality outside the breast by chance. Most abnormalities found are harmless and do not require further investigation or treatment. Very occasionally we do find something that needs further investigation. The radiologist will then contact your GP, who will discuss the results with you. If you would rather we did not tell you, you can indicate this on the consent form. We will then, of course, respect your wish. Sometimes the radiologist finds something that is life-threatening or could lead to permanent damage without medical treatment. For your protection or that of your immediate family members, we will still inform you and your GP of these results. A special committee will assess whether this is necessary.

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



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.

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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

