The second round of DENSE-2: **a second MRI examination**

Information brochure round 2

Versie 1.0 - 15 juli 2026

What is the DENSE-2 study?

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

Why have you received an invitation for a second MRI examination?

The DENSE-2 study consists of two rounds. This means we invite you for an MRI examination twice. You have already had your first MRI examination. We are now inviting you for a second MRI examination. This second round is important to determine how valuable it is to repeat the MRI examination every two years.

What can you expect if you participate in round 2?

The second round in 10 steps:

1) Breast cancer population screening. You had mammograms taken as part of the breast cancer population screening programme. Your latest mammograms show no evidence of breast cancer.

2) Invitation second round. You have received an invitation for a second MRI examination (by email or post).

3) Registration. You let the study team know, within 2 weeks of receiving the invitation, whether you are interested in participating in the second round of the DENSE-2 study. You can do this by using the link in your invitation email. Did you receive an invitation by post? Then send an email to dense-2@umcutrecht.nl or call 088-7553075 during consulation hours. The consultation hours can be found at www.dense-2.nl. See your invitation for more information.

4) Questionnaire. You complete a questionnaire. The study team uses this to check whether it is safe for you to have an MRI examination again.

5) Schedulling link. Within 24 hours of completing the questionnaire, you will receive either an email with a link to schedule a phone call, **or** an email with a link to schedule an appointment for an MRI examination directly.

Why are there two options?
You will receive a link to schedule a phone call if the study team wants to contact you by phone. This may be about your answers to the completed questionnaire, if you experienced a side effect during the first round of the study, or if you indicated that you would like to be contacted (see **step 6**).
If none of this applies, you will receive an email with a link to schedule an appointment for an MRI examination directly (see **step 7**).

6) Schedulling a phone call. You schedule a phone call, and the study team will call you at the agreed time and day. The study team checks whether it is safe for you to take part again and discusses any questions you may have. After this phone call, you will receive a link to schedule an appointment for an MRI examination. Go to step 7.

7) Scheduling the MRI examination. You schedule an appointment for an MRI examination. Please note! The hospitals set aside slots from regular care specifically for the DENSE-2 study. As a result, the number of available slots may be limited. We appreciated your understanding. You will receive a confirmation email from your appointment from the DENSE-2 study team, with further explanation.

8) Een MRI-onderzoek.

Prepartion of the MRI - 5 to 10 minutes:

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

The MRI examination itself - 5 minutes:

- You will lie in the MRI scanner for about 5 minutes.

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

10) End of DENSE-2. After completing all the questionnaires, your participation in the DENSE-2 study ends. Thank you very much for your participation!

Questionnaires

In the second round of the DENSE-2 study, we have 3 questionnaires:

1. Questionnaire 1: We use this to check whether it is safe for you to have an MRI examination again.
2. Questionnaire 2: We would like to understand what determines why women have very dense breast tissue, which is why we are asking you to complete this questionnaire again.
3. Questionnaire 3: We would like to know how you experienced your participation in the second round of the DENSE-2 study.

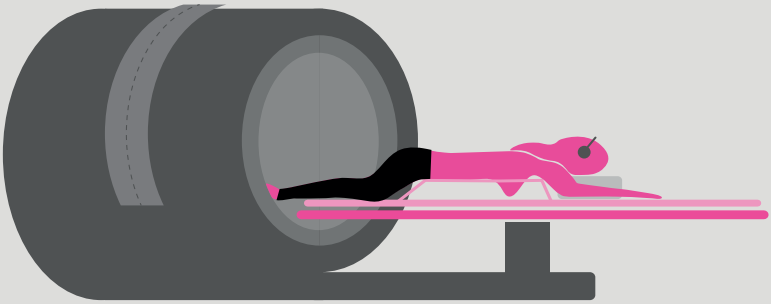
General information about the study

(you also received this information in the first round)

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 next page).
- 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 8).

Is an MRI examination safe?

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 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 have indicated 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.

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, like you received in the first round, 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.

Questions?

Our study team can best help you by email: dense-2@umcutrecht.nl. Is it not possible for you to mail? Then you can call during consultation hours: 088-7553075. At www.dense-2.nl you can find the times of the consulation hours.

www.dense-2.nl

Thank you very much for your participation!
On behalf of the DENSE-2 team