The second round of DENSE-2: **a second contrast mammogram**

Information brochure round 2

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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 contrast mammogram?

The DENSE-2 study consists of two rounds. This means we invite you for a contrast mammogram twice. You have already had your first contrast mammogram. We are now inviting you for a second contrast mammogram. This second round is important to determine how valuable it is to repeat the contrast mammogram 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 contrast mammogram (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 a contrast mammogram 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 a contrast mammogram 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 a contrast mammogram 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 a contrast mammogram. Go to step 7.

7) Scheduling the contrast mammogram. You schedule an appointment for a contrast mammogram. 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) A contrast mammogram. You go to the hospital for your appointment and have a contrast mammogram taken:

- The lab technician will insert an IV into your arm.
- If you had a phone call, 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 the contrast mammogram appointment. The lab technician taking the contrast mammogram will immediately know whether or not you can participate in the study. Did you not have a phone call? Then your kindey function does not need to be measured.
- You will be given contrast medium.
- A mammogram is taken, in the same way as in the population screening.

9) 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.

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:

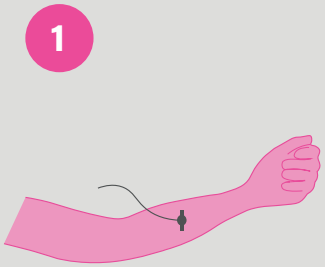
1. Questionnaire 1: We use this to check whether it is safe for you to have a contrast mammogram again.
2. Questionnaire 2: We would like to understand what determines why women have very dense breast tissue, which is why we are asking you to complete this questionnaire again.
3. Questionnaire 3: We 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 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.



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



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. Our website lists all possible side effect.

The most common **side effects** are:

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

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