Executive summary

Health Council of the Netherlands. Population Screening Act: pressure-guided compression for breast cancer screening. The Hague: Health Council of the Netherlands, 2011; publication no. 2011/25.

In cooperation with the National Reference Centre for Population Screening in Nijmegen and Amsterdam University Medical Centre, the Eastern Population Screening Hub in Enschede in the Netherlands would like to conduct research within the breast cancer screening programme. In compliance with the Population Screening Act, a licence is required for this from the Minister of Health, Welfare and Sport. On June 9th 2011, the Minister requested an advisory report from the Health Council of the Netherlands on this matter. To this end, the scientific soundness of the research proposal, its compliance with statutory rules on medical procedures, its benefit and risks, and its importance for public health were assessed by the Health Council's Committee on Population Screening against the provisions of the Population Screening Act.

The proposed research

As part of population screening for breast cancer women undergo mammography (an X-ray of the breast). This involves compressing the breast, which is an unpleasant and often painful experience. The standard force-guided compression does not take into account the size of the breast, whereas pressure-guided compression does. The applicant would like to investigate whether pressure-guided compression is less unpleasant, without any significant loss of quality of the mammogram at an acceptable radiation dose . For a woman who participates, the examination is equal to the regular population screening for breast cancer, except

that one of the four mammograms is made using pressure-guided compression and the woman concerned is asked a number of questions about the pain she experiences.

Scientific soundness

The Committee takes a positive view of the scientific soundness of the application. It is a well-designed study; there is sufficient substantiation for the number of participants and the anticipated results are relevant, quantifiable and testable. The women cannot know beforehand which method will be used. The first mammogram will be made using randomly either selected pressure-guided or force-guided compression. The radiological laboratory technicians will receive instructions to prevent them influencing the results. During assessment of the mammograms the radiologists will not know which were made with the force-guided and which with the pressure-guided compression technique.

Compliance with statutory rules on medical procedures

The recruitment of prospective participants in the study and the provision of information to them are in compliance with the intendment of the criteria. The women will be informed of the study's design and the pros and cons of participation. They will have sufficient opportunity and time to ask questions about the study and to decide whether they wish to participate.

Benefit and risk of the study

The Committee is of the opinion that the balance between the study's benefit and the risk to participants is acceptable. The study has no immediate benefit in the Committee's opinion. At the same time, the risk of a lower quality mammogram is negligible. Radiation exposure on account of pressure-guided compression can be no more than slightly higher and will in any case be within the certified range.

Importance for public health

The Committee is of the opinion that the study of less unpleasant examination methods in population screening is beneficial. If this study shows that pressure-guided compression is less unpleasant and provides mammography with similar quality, the findings will be important for all women who undergo this breast

examination every two years. The study can be carried out quickly and, given a positive result, pressure-guided compression can be readily introduced. The applicant has been in contact about this with the Centre for Population Screening (CVB) of the National Institute for Public Health and the Environment (RIVM).

Conclusion and recommendations

The Committee is of the opinion that the application is in compliance with the statutory criteria of the Population Screening Act. The Committee recommends the Minister of Health, Welfare and Sport to grant the requested licence.