
Executive summary

Health Council of the Netherlands. Population Screening Act: Use of Foil for Breast Compression in the Mammograph. The Hague: Health Council of the Netherlands, 2011; publication no. 2011/36.

The National Reference Centre for Population Screening in Nijmegen and the Population Screening East, Nijmegen location wish to conduct research within the population screening programme for breast cancer. Based on the Population Screening Act (WBO), a license is required from the Minister of Health, Welfare and Sport. She asked the Health Council for advise on the matter on 4 November 2011. To this end, the Committee on Population Screening of the Health Council examined the study proposal against the legal criteria in the WBO.

The planned study

There is a constant drive for improving existing techniques within the population screening programme. Changes may also be made to mammographs in order to improve screening. One manufacturer claims the use of foil on the compression plate and the so-called *bucky* makes the investigation more comfortable and increases the amount of breast tissue visible on the mammography. The applicants wish to study whether this is the case without the need for a higher dose of radiation.

Scientific integrity

The Committee rules positively on the scientific integrity of the project proposal described in the application. The study design is good, the required number of

participants is sufficiently substantiated and the expected outcomes are relevant, quantifiable and testable. Technicians are instructed in order to prevent results from being affected. Radiologists do not know which mammographs were made with and which without during assessment.

Agreement with legal rules for medical actions

Recruitment of and information provision for potential participants in the study meet legal criteria. The women are informed of the study structure and advantages and disadvantages of participation. They are given enough time to ask questions and decide on whether to participate in this study.

Usefulness and risks of the study

The Committee is of the opinion that the balance between usefulness of the study and the risk for participants is acceptable. Women who participate do not benefit directly from the study. At the same time, the standard screening programme is unaffected. An additional image is made of the breasts, which is later compared with the standard image by radiologists. Comparison of the image with or without foil only relates to image quality. The population screening is evaluated before then, and the results forwarded to the woman.

Public health interests

The Committee feels this study into improved breast cancer screening is not in conflict with public health interest.

Conclusion and recommendation

In the opinion of the Committee, the application meets the legal criteria outlined in the Population Screening Act (WBO). The Committee recommends the Minister of Health Welfare and Sport to grant the requested license.