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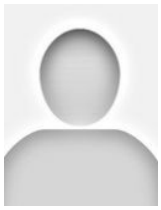
MRI in Women with Extremely Dense Breasts, Interview with Dr. Carla van Gils



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The first randomised controlled trial (RCT) on MRI and mammography in women with extremely dense breasts is underway in the Netherlands. Breast Cancer Screening With MRI in Women Aged 50-75 Years With Extremely Dense Breast Tissue: the DENSE Trial (**clinicaltrials.gov/ct2/show/NCT01315015**) aims to determine the cost-effectiveness of biennial screening with mammography and MRI compared to mammography alone in women aged 50-75 years and who show > 75% mammographic density (Emaus et al. 2015). Participants are recruited via the Dutch National Breast Cancer Screening Programme.

Breast Screening in the Netherlands

The Dutch National Breast Cancer Screening Programme was established in 1990.

Women in the Netherlands aged from 50 to 75 years (approximately 2.6 million women) are invited for a two-view mammogram every two years. The participation rate is approximately 80%; in 2012 1,008,644 women were screened (National Evaluation Team for Breast Cancer Screening 2014). Screening is available at 67 predominantly mobile mammography units. Two radiologists independently read all mammograms, and they must reach consensus to refer a woman for further clinical assessment. Since the programme was established mortality has decreased by more than 30%, due partly to screening-based early detection and treatment, and partly to improved treatment methods.

The DENSE Trial

HealthManagement.org spoke to Dr. Carla van Gils, Associate Professor of Clinical Epidemiology, University Medical Center Utrecht (UMCU), principal investigator of the DENSE trial.

The primary outcome measure of the DENSE trial will be the number of interval cancers in the MRI group and the control group. In order to be an effective screening strategy, the extra MRI screen-detected cancers have to be accompanied by a subsequent reduction in interval cancers. The intervention will be carried out for 3 screening rounds (ie six years). Secondary outcomes will include the number of MRI screen-detected cancers, a comparison of tumour size, stage and grade distributions diagnosed in both groups, mortality rate (estimated through simulation models), the positive predictive value of MRI, the cost-effectiveness of MRI and the impact of MRI screening on quality of life. The primary completion date is December 2019.

Why is the cut-off for density chosen greater than 75%?

The cut-off at greater than 75% equals the ACR density category 4: extremely dense breasts. This cut-off point is chosen, because the gain is expected to be higher for these women than for the women with heterogeneous density.

Why is contrast-enhanced MRI the modality under investigation?

We have chosen to investigate the value of MRI, because the sensitivity of MRI is higher than the sensitivity of other modalities such as ultrasound or tomosynthesis.

How will breast density be measured, and what information will women be given about their breast density?

Breast density is estimated by using a fully automatic and validated method (software) to estimate the volume of dense tissue in the breast. Women in the intervention group receive an invitation letter accompanied by an extensive information brochure. This brochure includes information on the effects of breast density on the sensitivity of mammography and breast cancer risk. The results of the intervention group will be compared to women who receive standard care. In the Dutch breast cancer screening programme it is not standard practice to inform women about their breast density.

How will cost-effectiveness be estimated?

Microsimulation Screening Analysis (MISCAN) is a breast cancer simulation model that has been developed for building models for cancer screening in a dynamic population. We will collect data on the costs of additional diagnostic work-up after positive MRI examination, breast cancer treatment and follow-up cancer care during the trial. Nonattendance at work and reduced work performance will be registered. The costs and effects will be calculated for a simulated cohort of 1 million women for a period of 10 years after the start of screening (using MISCAN). The

cost-effectiveness will be expressed as cost per life-year gained.

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