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## Japan Strategic Anti-cancer Randomized Trial (J-START) on the Effectiveness of Ultrasound for Breast Cancer Screening

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Screening mammography (SMG) is the only method to decrease breast cancer mortality based on randomized controlled trials (RCT) conducted in western countries more than 30 years ago. SMG also demonstrated its effectiveness in Japanese women when we retrospectively analyzed the survival data compared to clinical breast examination, especially for women aged 50 and over (*Cancer Science*, 2009). However, the accuracy of screening SMG is poor for breasts with high mammographic density, with sensitivity of 71% at women aged 40-49, much lower than 86% at women aged 50-59 (*Cancer Science*, 2008). Dense breasts are more common in Asian than in Western populations. An approach for complementing this weakness of SMG is now underway in Japan. This study is named as Japan Strategic Anti-cancer Randomized Trial (J-START) supported by the Third Term Comprehensive Control Research for Cancer from the Ministry of Health, Labor and Welfare.

Breast ultrasound (US) achieves better accuracy in breast cancer detection in dense breasts. However, specifications for equipment and procedures for examination and image reading have not been standardized. Also, accuracy of US and effectiveness in mortality reduction has not been proven. First in this study, we have established guideline for breast ultrasound procedure and categorization, and education course

that consists of 2 days, 16 hours lectures, hand on (for core needle biopsy) followed by evaluation tests using soft copy, movie motion. Second, J-START makes a randomized comparison, RCT between 2 groups of women aged 40-49, 50,000 persons in each arm, who are screened using either combined screening with SMG and US (intervention group) or SMG alone (control group). The primary endpoints are sensitivity and specificity, and the secondary endpoint is accumulated incidence rate of advanced breast cancer among two groups, although the outcome of cancer screening is reduction of the mortality rate. The planned study period is from April 2006 to March 2011, too short to confirm the mortality rate.

Breast cancer is still increasing in Asia, and the characteristics in these countries are similar to those in Japanese populations. The effort of Japan to establish evidence of US is important in the context of international contribution. With target number of study subjects being 100,000 persons in total, it is an unprecedentedly large-scale clinical trial in the world. Definitely, western countries are also looking for better ways to decrease breast cancer mortality at younger ages, with emphasizing the importance of J-START. Until August 2009, more than 50,000 women ages 40-49 have already registered in the trial.