

Study protocol

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Malmö Breast Tomosynthesis Screening Trial, MBTST

Principal investigator

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Synopsis

Study title	Malmö Breast Tomosynthesis Screening Trial, MBTST http://www.clinicaltrials.gov/ ; NCT01091545
Study phase	N/A
Background	Digital breast tomosynthesis, DBT (or 3D mammography) is a development of the currently used method in breast cancer screening, digital mammography, DM, that may increase the visibility of breast cancers and hence the detection.
Study setting	Within the population based screening programme in Malmö, Sweden. Skåne University Hospital Malmö, Unilabs Breast Centre.
Study design	Prospective, paired, one-armed study in a population-based screening program
Objectives	Primary objective: <ul style="list-style-type: none">• to investigate the sensitivity and specificity of breast cancer detection with DBT compared to DM. Secondary objectives: - to investigate the biological characteristics of the cancers in the trial by

	<p><i>mode of detection</i></p> <p><i>- to investigate the cost-effectiveness of DBT in screening</i></p>
Study population	<p>Inclusion criteria: a random selection of women aged 40-74 years invited to participate in mammography screening in Malmö</p> <p>Exclusion criteria: Pregnancy and/or women not understanding Swedish or English</p>
Methods	<p>Women will undergo both DBT in the medio-lateral oblique (MLO) projection and DM in MLO as well as cranio-caudal projection (CC). Reading of DBT and DM will be done independently. In addition, the DBT examination will be read together with the DM CC-view in order to assess the separate contribution of the DM CC-view. All studies will be double read.</p> <p>A two-year follow up and matching to the cancer registry will be performed to ascertain screening detected cancers and interval cancers.</p>
Assessments	<p>Women who are recalled for further assessment based on any method will be investigated according to so called triple assessment.</p>
Statistical considerations	<p>About 15,000 women are needed for this study in order to yield an 80% chance of getting a statistically significant outcome, i.e. detecting an increase in TPF and confirming that the FPF is within the acceptable limit of 20%.</p>
Potential benefit:	<p>An improved breast cancer detection with DBT may increase the benefits of breast cancer screening and further contribute to reduced mortality in breast cancer.</p>