

TMIST / EA1151

A Breast Cancer Screening Trial for Women

EA1151 Available Through ECOG-ACRIN Cancer Research Group

Tomosynthesis Mammographic Imaging Screening Trial (TMIST)

Patient Population

See Section 3.0 for Complete Eligibility Details

- Women must be age 45-74 at the time of study entry
- Women of childbearing potential must not be known to be pregnant or lactating
- Must be scheduled for, or have intent to schedule, a screening mammogram; must be able to tolerate digital breast tomosynthesis (TM) and full-field digital mammographic (DM) imaging required by protocol
- Must not have new symptoms/signs of benign or malignant breast disease (eg, bloody/clear nipple discharge, breast lump) based on physician physical exam/self breast exam that have not been previously worked up with imaging; women with physiologic nipple discharge or breast pain are eligible per protocol
- Must not have had a screening mammogram within the last 11 months prior to randomization
- Must not have previous personal history of breast cancer including ductal carcinoma in situ
- Must not currently have breast enhancements (eg, implants or radiopaque injections)
- One of the following 3 conditions must be met in order to be eligible for the annual screening regimen:
 - ◇ Women must be pre-menopausal; **OR**
 - ◇ Post-menopausal (defined per protocol) age 45-69 with any of the following 4 risk factors:
 - ◆ Dense breasts (BIRADS categories c-heterogeneously dense/d-extremely dense), or
 - ◆ At least 1 benign breast biopsy with a diagnosis of LCIS or atypia of any kind, or
 - ◆ Family history of breast cancer (1st degree relative) or unknown family history, or participant positive genetic testing for deleterious genes that indicate an increased risk for breast cancer, or
 - ◆ Currently on hormone therapy (see protocol), **OR**
 - ◇ Post-menopausal age 70-74 with either of the following 3 risk factors:
 - ◆ Dense breasts (BIRADS categories c/d)
 - ◆ At least 1 benign breast biopsy with a diagnosis of LCIS or atypia of any kind, or
 - ◆ Currently on hormone therapy

Imaging Plan

See Section 5.0 for Complete Details

Institutions will be selected to participate and must be able to perform all imaging procedures in a mammography clinic that routinely performs both TM and DM in the same facility

Arm A- Digital Mammography (DM):

- Bilateral digital screening mammogram with standard craniocaudal and mediolateral oblique views (additional images to cover all portions of the breast in women with large breasts will be allowed)
- Imaging should be performed within 30 days of randomization and repeated annually for up to 4 years or biennially for up to 4 years, or until cancer is detected

Arm B- Tomosynthesis (TM):

- Manufacturer-defined screening TM with the exact configuration of TM images being determined by local clinical practice
 - ◇ There are no specific requirements for images to be utilized except that the machines are FDA or CE approved
- Imaging should be performed within 30 days of randomization and repeated annually for up to 4 years or biennially for up to 4 years, or until cancer is detected

Notes:

- *Examinations that fall outside of the desired intervals described per protocol for each screening time point will still be considered part of the study, and not an actionable deviation*
- *Women who are screened with the wrong modality should be returned to their assigned modality for subsequent screens*
- *All participating scanners must be accredited under the US Mammography Quality Standards Act (or equivalent)*
- *All radiologist readers must be qualified to perform TM and DM reads per MQSA guidelines (or equivalent)*
- *Data will be collected for at least 3 and up to 8 years*

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) <https://open.ctsu.org>

Protocol Information

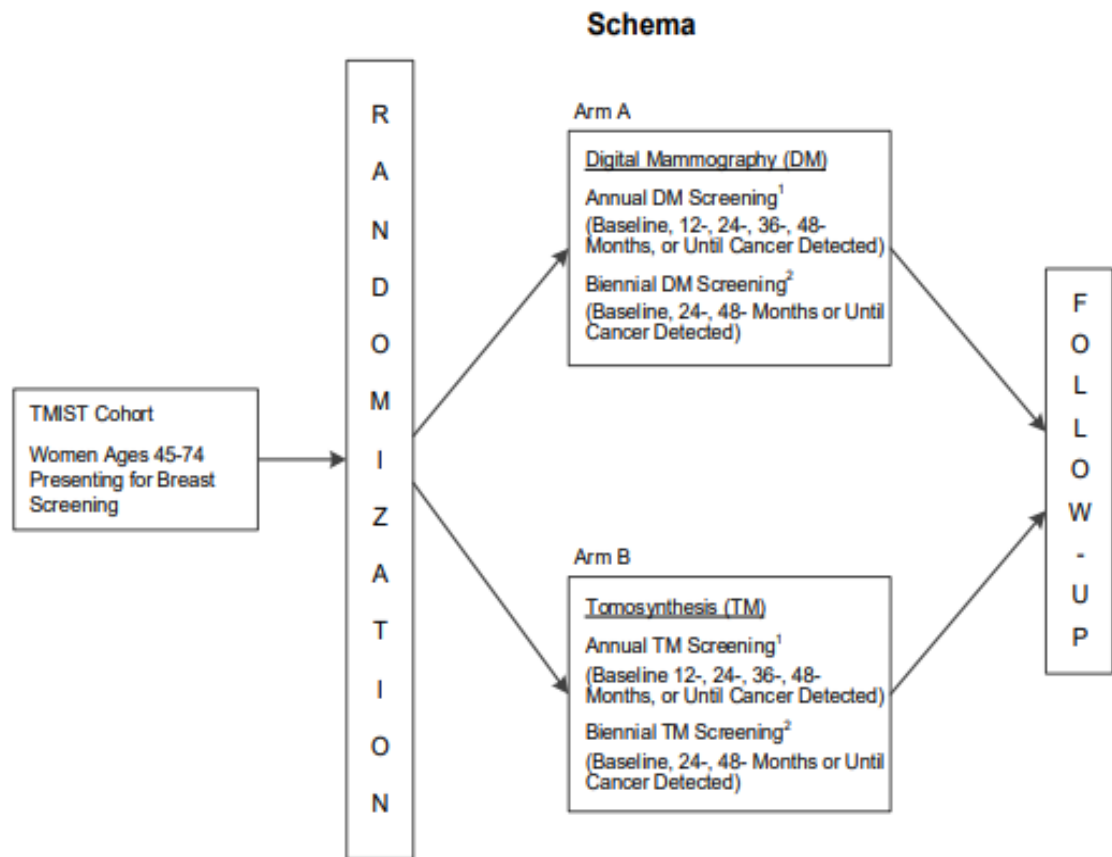
ECOG-ACRIN Operations-Boston: 857-504-2900, <http://ecog-acrin.org> (Member Login)

Please Enroll Your Eligible Patients!

Study Chair:
Etta D. Pisano, MD

TMIST / EA1151

EA1151 Available Through ECOG-ACRIN Cancer Research Group
Tomosynthesis Mammographic Imaging Screening Trial (TMIST)



Accrual Goal = 128,905

1. All premenopausal women will undergo annual screening.
2. Postmenopausal women will undergo biennial screening unless they have any specific risk factors as listed in Section 3.1.10.
3. Suspicious lesions will undergo diagnostic imaging, biopsy, cancer diagnosis, and/or Tx decision making per local standard practice.
4. Tissue will be collected for analysis for all women who undergo breast biopsy during protocol screening and clinical follow-up periods.
5. On detection and confirmation of breast cancer, participants will cease protocol screening and begin annual follow-up.
6. Follow up will last for at least 3 and up to 8 years after study entry.

TMIST

ECOG-ACRIN
cancer research group