Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Test de dépistage par mammographie par tomosynthèse (TMIST)
Protocole ID	MAC.22
ClinicalTrials.gov ID	NCT03233191
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Diagnostic
Institution	CIUSSS DU NORD-DE-L'ILE-DE-MONTREAL HOPITAL DU SACRE-COEUR-DE-MONTREAL 5400 boul. Gouin Ouest, Montréal, QC, H4J1C5
Ville	
Investigateur principal	Dre Caroline Samson
Coordonnateur	Michel Archambault 514-338-2222 poste 3739
Statut	Actif en recrutement
But étude	This randomized phase III trial studies digital tomosynthesis mammography and digital mammography in screening patients for breast cancer. Screening for breast cancer with tomosynthesis mammography may be superior to digital mammography for breast cancer screening and may help reduce the need for additional imaging or treatment.
Critères d'éligibilité	• Women of childbearing potential must not be known to be pregnant or lactating • Patients must be scheduled for, or have intent to schedule, a screening mammogram • Patients must be able to tolerate digital breast tomosynthesis and full-field digital mammographic imaging required by protocol, to be performed at an American College of Radiology Imaging Network (ACRIN)-qualified facility • Patients must be willing and able to provide a written informed consent • Patients must not have symptoms or signs of benign or malignant breast disease (eg, nipple discharge, breast lump) warranting a diagnostic rather than a screening mammogram, and/or other imaging studies (eg, sonogram); patients with breast pain are eligible as long as other criteria are met • Patients must not have had a screening mammogram within the last 11 months prior to date of randomization • Patients must not have previous personal history of breast cancer including ductal carcinoma in situ • Patients must not have breast enhancements (e.g., implants or injections) • ANNUAL SCREENING REGIMEN ELIGIBILITY CHECK • To be eligible for inclusion in the annual screening regimen one of the following three conditions must be met in addition to the eligibility criteria above: • Patients are pre-menopausal; OR • Post-menopausal aged 45-69 with any of the following three risks factors: • Dense breasts (BIRADS density categories c-heterogeneously dense or d-extremely dense), or • Family history of breast cancer (first degree relative with breast cancer), or, positive genetic testing for any deleterious genes that indicate an increased risk for breast cancer, or • Currently on hormone therapy; OR • Post-menopausal ages 70-74 with either of the following two risk factors: • Dense breasts (BIRADS density categories c-heterogeneously dense or d-extremely dense), or • Currently on hormone therapy • Postmenopausal women are defined as those with their last menstrual period more than 12 months prior to study entry; for the purpose of defining menopausal status for women who have had surgical cessation of their periods, women who no longer have menses due to hysterectomy and oophorectomy will be considered postmenopausal; women who no longer

	have menses due to hysterectomy without oophorectomy will be considered premenopausal until age 52 and postmenopausal thereafter • All other postmenopausal women are eligible for inclusion in the biennial screening regimen • For those women who cannot be assigned to annual or biennial screening at the time of study entry and randomization because they are postmenopausal, have no family history or known deleterious breast cancer mutation, are not on hormone therapy AND have not had a prior mammogram, breast density will be determined by the radiologist?s recording of it at the time of interpretation of the first study screening examination, either DM or TM; for those who are randomized to TM, radiologists will assign BI-RADS density through review of the DM or synthetic DM portion of the TM examination; such women cannot be part of the planned stratification by screening frequency and are expected to represent far less than 1% of the Tomosynthesis Mammographic Imaging Screening Trial (TMIST) population • Breast density will be determined by prior mammography reports, when available; all other risk factors used to determine patient eligibility for annual or biennial screening will be determined by subject self-report
Critères d'exclusion	