Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Un essai clinique de phase III randomisé qui évalue la paroi de la cage thoracique post-mastectomie et la radiothérapie ganglionnaire régionale post-lumpectomie chez les patientes qui présentent avec des ganglions axillaires histologiquement positifs, mais qui deviennent des ganglions axillaires histologiquement négatifs après une chimiothérapie néoadjuvante.
Protocole ID	NSABP B-51, RTOG 1304
ClinicalTrials.gov ID	NCT01872975
Type(s) de cancer	Sein
Phase	Phase III
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dr Michael Yassa
Coordonnateur	Linda Roy-Huneault 514-252-3400 poste 3227
Statut	Fermé
But étude	This randomized phase III trial studies standard or comprehensive radiation therapy in treating patients with early-stage breast cancer who have undergone surgery. Radiation therapy uses high-energy x rays to kill tumor cells. It is not yet known whether comprehensive radiation therapy is more effective than standard radiation therapy in treating patients with breast cancer
Critères d'éligibilité	• The patient must have signed and dated an Institutional Review Board (IRB)-approved consent form that conforms to federal and institutional guidelines • The patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Patient must have clinically T1-3, N1 breast cancer at the time of diagnosis (before neoadjuvant therapy); clinical axillary nodal involvement can be assessed by palpation, ultrasound, CT scan, magnetic resonance imaging (MRI), positron emission tomography (PET) scan, or PET/CT scan • Patient must have had pathologic confirmation of axillary nodal involvement at presentation (before neoadjuvant therapy) based on either a positive fine needle aspirate (FNA) (demonstrating malignant cells) or positive core needle biopsy (demonstrating invasive adenocarcinoma); the FNA or core needle biopsy can be performed either by palpation or by image guidance; documentation of axillary nodal positivity by sentinel node biopsy (before neoadjuvant therapy) is not permitted • Patients must have had estrogen receptor (ER) analysis performed on the primary breast tumor before neoadjuvant therapy according to current American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guideline recommendations for hormone receptor testing; if negative for ER, assessment of progesterone receptor (PgR) must also be performed according to current ASCO/CAP guideline recommendations for hormone receptor testing (http://www.asco.org) • Patients must have had HER2 testing performed on the primary breast tumor before neoadjuvant chemotherapy according to the current ASCO/CAP guideline recommendations for human epidermal growth factor receptor 2 testing in Breast Cancer (http://www.asco.org); patients who have a primary tumor that is either HER2-positive or HER2-negative are eligible • Patient must have completed a minimum of 12 weeks of standard neoadjuvant chemotherapy consisting of an anthracycline and/or taxane-based regimen • For patients who receive adjuvant chemotherapy after surgery, a maximum of 12 weeks of intended chemotherapy may be administered but must be completed before randomization; (if treatment delays occur, chemotherapy must be completed within 14 weeks); the dose and schedule of the adjuvant chemotherapy are at the investigator's discretion; Note: It is preferred that all intended chemotherapy be administered in the neoadjuvant setting

	• Patients with HER2-positive tumors must have received neoadjuvant trastuzumab or other anti-HER2 therapy (either with all or with a portion of the neoadjuvant chemotherapy regimen), unless medically contraindicated
	• At the time of definitive surgery, all removed axillary nodes must be histologically free from cancer; acceptable procedures for assessment of axillary nodal status at the time of surgery include:
	  • Axillary node dissection
	  • Sentinel node biopsy alone or
	  • Sentinel node biopsy followed by axillary node dissection
	  • Note: Patients are eligible whether there is residual invasive carcinoma in the surgical breast specimen or whether there is evidence of pathologic complete response; patients who are found to be pathologically node-positive at the time of surgery, based on sentinel node biopsy alone, are candidates for A011202, a study developed by the Alliance in Oncology, an NCI Cooperative Group; if A011202 is open at the investigator's institution, patients should be approached about participating in the A011202 study
	• Patients with pathologic staging of ypN0(i+) or ypN0(mol+) are eligible (Note: Postneoadjuvant therapy is designated with a "yp" prefix.)
	• Patient who have undergone either a total mastectomy or a lumpectomy are eligible
	• For patients who undergo lumpectomy, the margins of the resected specimen or re-excision must be histologically free of invasive tumor and DCIS as determined by the local pathologist; additional operative procedures may be performed to obtain clear margins; if tumor is still present at the resected margin after re-excision(s), the patient must undergo total mastectomy to be eligible; (patients with margins positive for lobular carcinoma in situ [LCIS] are eligible without additional resection)
	• For patients who undergo mastectomy, the margins must be histologically free of residual (microscopic or gross) tumor
	• The interval between the last surgery for breast cancer (including re-excision of margins) and randomization must be no more than 56 days; also, if adjuvant chemotherapy was administered, the interval between the last chemotherapy treatment and randomization must be no more than 56 days
	• The patient must have recovered from surgery with the incision completely healed and no signs of infection
	• If adjuvant chemotherapy was administered, chemotherapy-related toxicity that may interfere with delivery of radiation therapy should have resolved

Critères d'exclusion	• Definitive clinical or radiologic evidence of metastatic disease • T4 tumors including inflammatory breast cancer • Documentation of axillary nodal positivity before neoadjuvant therapy by sentinel node biopsy alone • N2 or N3 disease detected clinically or by imaging • Patients with histologically positive axillary nodes post neoadjuvant therapy • Patients with microscopic positive margins after definitive surgery • Synchronous or previous contralateral invasive breast cancer or DCIS; (patients with synchronous and/or previous contralateral LCIS are eligible) • Any prior history, not including the index cancer, of ipsilateral invasive breast cancer or ipsilateral DCIS treated with radiation therapy; (patients with synchronous or previous ipsilateral LCIS are eligible) • History of non-breast malignancies (except for in situ cancers treated only by local excision and basal cell and squamous cell carcinomas of the skin) within 5 years prior to randomization • Any radiation therapy for the currently diagnosed breast cancer prior to randomization • Any continued use of sex hormonal therapy, e.g., birth control pills, ovarian hormone replacement therapy; patients are eligible if these medications are discontinued prior to randomization • Prior breast or thoracic radiation therapy (RT) for any condition • Active collagen vascular disease, specifically dermatomyositis with a creatinine phosphokinase (CPK) level above normal or with an active skin rash, systemic lupus erythematosus, or scleroderma • Pregnancy or lactation at the time of study entry; (Note: Pregnancy testing must be performed within 2 weeks prior to randomization according to institutional standards for women of childbearing potential) • Other non-malignant systemic disease that would preclude the patient from receiving study treatment or would prevent required follow-up • Psychiatric or addictive disorders or other conditions that, in the opinion of the investigator, would preclude the patient from meeting the study requirements