



Essai Clinique

Généré le 04 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 DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dr Mark Basik
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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	<ul style="list-style-type: none">• 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