Essai Clinique

Généré le 05 mai 2025 à partir de

Titre	Une étude randomisée de phase 3 visant à comparer la lymphadénectomie axillaire à la radiothérapie axillaire chez des sujets atteints de cancer du sein (cT1-3 N1) touchant les ganglions sentinelles après la chimiothérapie néoadjuvante
Protocole ID	MAC.19
ClinicalTrials.gov ID	NCT01901094
Type(s) de cancer	Sein
Phase	Phase III
Stade	Néoadjuvant ou adjuvant
Type étude	Traitement
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
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Statut	Fermé
But étude	This randomized phase III trial studies axillary lymph node dissection to see how well it works compared to axillary radiation therapy in treating patients with node-positive breast cancer treated with neoadjuvant chemotherapy followed by surgery. Lymph node dissection may remove cancer cells that have spread to nearby lymph nodes in patients with breast cancer. Radiation therapy uses high-energy x-rays to kill tumor cells. This study will evaluate whether radiation therapy is as effective as lymph node dissection.
Critères d'éligibilité	• Patients ≥ 18 years of age • Clinical stage T1-3 N1 M0 breast cancer at diagnosis (prior to the start of neoadjuvant chemotherapy) by American Joint Committee on Cancer (AJCC) staging 7th edition • No inflammatory breast cancer • No other malignancy within 5 years of registration with the exception of basal cell or squamous cell carcinoma of the skin treated with local resection only or carcinoma in situ of the cervix • All patients must have had an axillary ultrasound with fine needle aspiration (FNA) or core needle biopsy of axillary lymph nodes documenting axillary metastasis at the time of diagnosis, prior to or at most 14 days after starting neoadjuvant chemotherapy. Note: Biopsy of intramammary nodes does not fulfill eligibility criteria. • Patients must have had estrogen receptor, progesterone receptor and human epidermal growth factor receptor 2 (HER2) status by immunohistochemistry [IHC] and/or fluorescence in situ hybridization [FISH] evaluated on diagnostic core biopsy prior to start of neoadjuvant chemotherapy. Note: If HER2 status has not been clearly determined (ie equivocal/indeterminate), then patients should not be enrolled. • Patients must have completed all planned chemotherapy prior to surgery. Sandwich chemotherapy is not allowed (i.e. chemotherapy planned to be given after surgery). Patients must have completed at least 4 cycles of neoadjuvant chemotherapy consisting of an anthracycline and/or taxane-based regimen without evidence of disease progression in the breast or the lymph nodes. NOTE: Delays/dose modifications due to toxicities/adverse events are allowed as long as a minimum of 4 cycles of neoadjuvant chemotherapy is administered. More than 4 cycles of NAC may be administered at the discretion of the treating medical oncologist. • Patients with HER-2 positive tumors must have received neoadjuvant trastuzumab or trastuzumab + pertuzumab or other approved anti-HER-2 therapy (either with all or with a

portion of the neoadjuvant chemotherapy regimen). Therapy must be Food and Drug Administration (FDA)-approved targeted anti-HER2 therapy, but additional therapies are allowed as are non-trastuzumab regimens if administered in the context of an Institutional Review Board (IRB)-approved clinical trial.
- All patients must have a clinically negative axilla (no palpable lymph nodes or bulky adenopathy) on physical examination documented at the completion of neoadjuvant chemotherapy. NOTE: An ultrasound of the axilla is not required at completion of neoadjuvant chemotherapy. If performed, its findings do NOT impact eligibility.
- No neoadjuvant endocrine therapy
- No neoadjuvant radiation therapy
- No sentinel lymph node (SLN) surgery/excisional biopsy for pathological confirmation of axillary status prior to or during neoadjuvant chemotherapy
- No prior history of ipsilateral breast cancer (invasive disease or ductal carcinoma in situ [DCIS]). Lobular carcinoma in situ (LCIS) and benign breast disease is allowed.
- No prior ipsilateral axillary surgery, such as excisional biopsy of lymph node(s) or treatment of hidradenitis.
- No history of prior or concurrent contralateral invasive breast cancer. Benign breast disease, LCIS or DCIS of contralateral breast is allowed.
- Patients must not be pregnant or nursing. A negative pregnancy test is required prior to registration for women of childbearing potential. Note: Peri-menopausal women must be amenorrheic for > 12 months to be considered not of childbearing potential.
- Eastern Cooperative Oncology Group (ECOG) (Zubrod) performance status 0-1.

Intra-Operative Registration/Randomization Criteria:

1. Breast surgery (lumpectomy or mastectomy) and sentinel lymph node surgery must be completed within 56 days of the completion of neoadjuvant chemotherapy.
2. A minimum of 1 sentinel node and a maximum of 6 total nodes (sentinel + non-sentinel) are identified and excised by the surgeon. Patients who do not have an identifiable sentinel lymph node will not proceed to Registration/Randomization.
3. At least one lymph node (sentinel or non-sentinel) with a metastasis greater than 0.2 mm in greatest dimension identified on intra-operative pathologic assessment. Note: Isolated tumor cells (metastases less than or equal to 0.2 mm) will be treated as node negative disease (N0i+). Axillary lymph node dissection [ALND] is not to be performed prior to Registration/Randomization.

Post-Operative Registration/Randomization Criteria: 1. For cases where ALND has not been performed and one of the following is true:

- intra-operative evaluation of sentinel lymph node could not be/was not performed and final pathology identified a positive lymph node (sentinel or non-sentinel) with metastasis greater than 0.2 mm on hematoxylin and eosin stain (H & E) OR
- lymph node (sentinel or non-sentinel) considered negative on intra-operative evaluation was found to be positive on final pathology (with metastasis greater than 0.2 mm on H & E)
    - Breast surgery (lumpectomy or mastectomy) and sentinel lymph node surgery must be completed within 56 days of the completion of neoadjuvant chemotherapy.
    - At least one lymph node (sentinel or non-sentinel) with a metastasis greater than 0.2 mm in greatest dimension identified by H&E staining on final pathology (for cases where intra-operative evaluation was not performed, or was negative and completion dissection was not performed).
    - Among the minimum of 1 and the maximum of 6 nodes (sentinel or non-sentinel) identified and excised by the surgeon, no more than 8 lymph nodes (sentinel and non-sentinel) were found by the pathologists to have been actually excised. Note: Isolated tumor cells (metastases less than or equal to 0.2 mm) will be treated as node negative disease (N0i+).
    - For those patients who also undergo contralateral breast surgery, if invasive disease is found in the contralateral breast, the patient is not eligible for registration/randomization.

Critères d'exclusion