Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients With Clinical/Radiologic Complete Response After Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment Without Surgery
Protocole ID	BR005
ClinicalTrials.gov ID	NCT03188393
Type(s) de cancer	Sein
Phase	Phase II
Type étude	Autre
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 phase II trial studies how well biopsy of breast after chemotherapy works in predicting pathologic response in patients with stage II-IIIA breast cancer undergoing breast conserving surgery. Tumor tissue collected from biopsy before surgery may help to check if chemotherapy destroyed the breast cancer cells and may be compared to the tumor removed during surgery to check if they are the same.
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 • Patients must have had ER analysis performed on the primary breast tumor collected prior to 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 • Patients must have had HER2 testing performed on the primary breast tumor collected prior to neoadjuvant chemotherapy according to the current ASCO/CAP guideline recommendations for human epidermal growth factor receptor 2 testing in breast cancer; patients who have a primary tumor that is HER2-positive, HER2-equivocal, or HER2-negative are eligible • Patients must have a biopsy marker placed within the tumor bed with imaging confirmation (preferably mammogram but ultrasound or magnetic resonance imaging [MRI] is acceptable) of marker placement prior to neoadjuvant chemotherapy • Patients with operable focal or multifocal (T1-T3, stage II and IIIA invasive ductal carcinoma [all receptor phenotypes]), and who have completed neoadjuvant chemotherapy with a clinical complete response (by clinical examination) • Patients must have achieved a complete or near complete radiologic tumor response on breast imaging with mammogram, ultrasound, and MRI • Patients must be undergoing breast conserving therapy • Patient must be able to undergo stereotactic-vacuum-assisted breast biopsy with clip placement after completion of neoadjuvant chemotherapy • Patient must have completed a minimum of 8 weeks of standard neoadjuvant chemotherapy consisting of an anthracycline and/or taxane-based regimen • Patients with HER2-positive tumors must have received neoadjuvant anti-HER2 therapy (either with all or with a portion of the neoadjuvant chemotherapy regimen), unless medically

	contraindicated • Patients treated with PD-1 or PD-L1 inhibitors, CDK 4/6 inhibitors, or other immune-based therapy are eligible • Patients with previous contralateral invasive breast cancer treated with anti-cancer therapy are eligible
Critères d'exclusion	• T4 tumors including inflammatory breast cancer • Patients with metastatic disease • Lumpectomy performed prior to study entry • Patients with any history of prior radiation therapy in the affected breast • Patients with synchronous ipsilateral invasive breast cancer or any prior history of ipsilateral invasive breast cancer; (patients with previous ipsilateral/contralateral DCIS or previous contralateral invasive breast cancer treated with anti-cancer therapy are eligible) • Patients with invasive lobular carcinoma • Patients who have multicentric disease • Patients treated with neoadjuvant hormonal therapy only are not eligible • Patients who are medically unfit to undergo surgical resection • Patients without breast biopsy marker documented by imaging at tumor bed site prior to initiation of neoadjuvant therapy • Patients who did not undergo trimodality imaging after completion of neoadjuvant chemotherapy (breast ultrasound, MRI, and mammography) • Patients with one or more of the following imaging criteria from any of the 3 imaging modalities after completion of neoadjuvant chemotherapy (NCT) are not eligible: • Mammogram with malignant appearing calcifications or mass > 1 cm; or • Ultrasound with a hypoechoic area > 2 cm; or • Breast MRI demonstrating a residual mass with rapid rise and washout type III kinetics. • Psychiatric or addictive disorders or other conditions that, in the opinion of the investigator, would preclude the patient from meeting the study requirements or interfere with interpretation of study results • Pregnancy or lactation at the time of study registration; (Note: Pregnancy testing according to institutional standards for women of childbearing potential must be performed within 2 weeks prior to study registration)