


Titre	Essai randomisé de radiothérapie locorégionale hypofractionnée dans le cancer du sein et le lymphœdème
Protocole ID	RHEAL
ClinicalTrials.gov ID	<a href="#">NCT04228991</a>
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL  PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dr Michael Yassa
Coordonnateur	Josée Abi-Saad 514-252-3400 poste 3227
Statut	Actif en recrutement
But étude	The primary objective is to determine if hypofractionated radiotherapy (RT) delivered over 1 week to the breast and regional nodes (supraclavicular, axillary and internal mammary) following breast conserving surgery (BCS), or to the chest wall and regional nodes following mastectomy, is non-inferior to conventional fractionation delivered over 3 weeks in patients with node positive breast cancer.
Critères d'éligibilité	<ul style="list-style-type: none"><li>• Newly diagnosed invasive carcinoma of the breast.</li><li>• Treated with definitive surgery (BCS or mastectomy with nodal staging using SLNB or ALND) with clear margins of excision. Note: *Patients with limited positive posterior margin where disease is resected to chest wall or limited positive anterior margin where disease is resected to dermis are eligible.</li><li>• Breast cancer stage after definitive surgery. Note: †Patients who are histologically node positive prior to chemotherapy and who have complete response in the lymph nodes are eligible.<ul style="list-style-type: none"><li>• if neoadjuvant chemotherapy was not administered: pathologic stage T1-3, N1-2</li><li>• if neoadjuvant chemotherapy was administered: clinical stage T1-3, N1-2 (histologically node positive) and pathologic stage T0-3, N0-2†</li></ul></li><li>• No evidence of metastatic disease.</li><li>• Candidate for locoregional radiotherapy.</li></ul>
Critères d'exclusion	<ul style="list-style-type: none"><li>• Age &lt; 18 years.</li><li>• Clinical stages T4 and/or N3.</li><li>• Clinical lymphedema in the ipsilateral arm or breast/chest wall.</li><li>• Synchronous or previous contralateral breast cancer.</li><li>• Breast reconstruction.</li><li>• History of non-breast malignancy within the last 5 years other than non-melanoma skin cancer or treated in-situ carcinoma.</li><li>• Previous radiotherapy to the ipsilateral breast or chest wall or serious non-malignant disease e.g. scleroderma, severe lung or heart disease that would preclude radiotherapy.</li><li>• Known pregnancy or currently lactating.</li><li>• Geographic inaccessibility for follow-up.</li><li>• Inability to provide informed consent.</li></ul>