


Titre	Essai randomisé de radiothérapie locorégionale hypofractionnée dans le cancer du sein et le lymphœdème
Protocole ID	RHEAL
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT04228991">NCT04228991</a>
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Institution	CISSS DE CHAUDIERE-APPALACHES  HOTEL-DIEU DE LEVIS 143 rue Wolfe, Lévis, QC, G6V 3Z1
Ville	
Investigateur principal	Dre Anne Dagnault
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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	<ol style="list-style-type: none"><li>1. Newly diagnosed invasive carcinoma of the breast.</li><li>2. 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>3. Breast cancer stage after definitive surgery.<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>Note: †Patients who are histologically node positive prior to chemotherapy and who have complete response in the lymph nodes are eligible.</li><li>4. No evidence of metastatic disease.</li><li>5. Candidate for locoregional radiotherapy.</li></ol>
Critères d'exclusion	<ol style="list-style-type: none"><li>1. Age &lt; 18 years.</li><li>2. Clinical stages T4 and/or N3.</li><li>3. Clinical lymphedema in the ipsilateral arm or breast/chest wall.</li><li>4. Synchronous or previous contralateral breast cancer.</li><li>5. Breast reconstruction.</li><li>6. History of non-breast malignancy within the last 5 years other than non-melanoma skin cancer or treated in-situ carcinoma.</li><li>7. 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>8. Known pregnancy or currently lactating.</li><li>9. Geographic inaccessibility for follow-up.</li><li>10. Inability to provide informed consent.</li></ol>