Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Essai randomisé de radiothérapie locorégionale hypofractionnée dans le cancer du sein et le lymphœdème
Protocole ID	RHEAL
ClinicalTrials.gov ID	NCT04228991
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
Coordonnateur	Pierre Bédard 418-835-7121
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	1. Newly diagnosed invasive carcinoma of the breast. 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. 3. Breast cancer stage after definitive surgery. • if neoadjuvant chemotherapy was not administered: pathologic stage T1-3, N1-2 • if neoadjuvant chemotherapy was administered: clinical stage T1-3, N1-2 (histologically node positive) and pathologic stage T0-3, N0-2† Note: †Patients who are histologically node positive prior to chemotherapy and who have complete response in the lymph nodes are eligible. 4. No evidence of metastatic disease. 5. Candidate for locoregional radiotherapy.
Critères d'exclusion	1. Age < 18 years. 2. Clinical stages T4 and/or N3. 3. Clinical lymphedema in the ipsilateral arm or breast/chest wall. 4. Synchronous or previous contralateral breast cancer. 5. Breast reconstruction. 6. History of non-breast malignancy within the last 5 years other than non-melanoma skin cancer or treated in-situ carcinoma. 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. 8. Known pregnancy or currently lactating. 9. Geographic inaccessibility for follow-up. 10. Inability to provide informed consent.