


Titre	Essai randomisé de phase III d'une radiothérapie hypofractionnée post-mastectomie et reconstruction mammaire
Protocole ID	MAC.23
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT03414970">NCT03414970</a>
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Autre
Institution	CISSS DE L'OUTAOUAIS  HOPITAL DE GATINEAU 909 Boulevard La Vérendrye, Gatineau, QC, J8P 7H2
Ville	Gatineau
Investigateur principal	Dr Robert Archambault
Coordonnateur	Isabelle Laforest 819-966-6100 poste 3669
Statut	Fermé
Date d'activation	15-01-2019
But étude	This randomized phase III trial studies how well hypofractionated radiation therapy works in preventing recurrence in patients with stage IIa-IIIa cancer who have undergone mastectomy. Hypofractionated radiation therapy delivers higher doses of radiation therapy over a shorter period of time and may kill more tumor cells that remain after surgery and have fewer side effects.
Critères d'éligibilité	<ul style="list-style-type: none"><li>• Histologically confirmed invasive carcinoma of the breast of any of the following histologies (ductal, lobular, mammary, medullary, or tubular); in-situ disease alone is not allowed</li><li>• Final American Joint Committee on Cancer (AJCC) stage IIa - IIIa (pathologic stage T0N1a-2a, T1N1a-2a, T2N1a-2a, T3N0-2a, all M0 status); pathological stage for all patients not receiving neoadjuvant chemotherapy; higher of the clinical or pathological T and N stage, if receiving neoadjuvant chemotherapy; patients with pathological N0 at the time of mastectomy are only eligible if biopsy-proven clinically N1 or N2 disease is documented prior to induction chemotherapy</li><li>• No prior radiation therapy to the chest, neck or axilla</li><li>• No prior history of ipsilateral breast cancer (invasive disease or ductal breast carcinoma in situ [DCIS]); lobular carcinoma in situ (LCIS) and benign breast disease is allowed</li><li>• No history of prior or concurrent contralateral invasive breast cancer; benign breast disease, LCIS or DCIS of contralateral breast is allowed</li><li>• No active collagen vascular diseases, such as: systemic lupus erythematosus, scleroderma, or dermatomyositis</li><li>• Negative inked histologic margins from mastectomy pathology (no invasive cells at margin)</li><li>• No significant post mastectomy complications requiring an unplanned re-operation or admission for intravenous (IV) antibiotics; re-operation for margins evaluation, nodal completion and routine reconstruction is acceptable</li><li>• Radiation oncologist intends to treat all target volumes and respect all normal tissues in accordance with the dosimetric constraints described (simulation before registration recommended)</li><li>• Radiation oncologist is planning to treat regional lymph nodes including internal mammary nodes and meet acceptable protocol dosimetric requirements</li><li>• Radiation oncologist is NOT planning to utilize a chest wall/scar boost</li><li>• Patient must have undergone immediate reconstruction at the time of mastectomy or be planning to undergo reconstruction within 8 months after radiation</li><li>• For patients with diabetes, hemoglobin A1C test must have been performed <math>\leq</math> 90 days prior to</li></ul>

	<p>registration</p> <ul style="list-style-type: none"><li>• No co-existing medical conditions with life expectancy &lt; 5 years</li><li>• 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</li><li>• Negative serum or urine beta-human chorionic gonadotropin (HCG) in women of child-bearing potential =&lt; 7 days prior to registration; a female of childbearing potential is a sexually mature female who has not undergone a hysterectomy or bilateral oophorectomy and has not been naturally postmenopausal for at least 12 consecutive months</li><li>• Women of child-bearing potential must agree to utilize a form of birth control or agree to undergo sexual abstinence during radiation therapy</li><li>• Eastern Cooperative Oncology Group (ECOG) (Zubrod) performance status 0-1</li></ul>
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Critères d'exclusion	
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