Essai Clinique

Généré le 22 sept. 2021 à partir de

Titre	Essai de phase III à répartition aléatoire évaluant la radiothérapie hypofractionnée postmastectomie avec reconstruction mammaire
Protocole ID	MAC.23
ClinicalTrials.gov ID	NCT03414970
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Traitement
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dr Michael Yassa
Coordonnateur	Véronique Tran 514-252-3400 poste 3227
Statut	Fermé
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	• 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 • 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 • No prior radiation therapy to the chest, neck or axilla • 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 • No history of prior or concurrent contralateral invasive breast cancer; benign breast disease, LCIS or DCIS of contralateral breast is allowed • No active collagen vascular diseases, such as: systemic lupus erythematous, scleroderma, or dermatomyositis • Negative inked histologic margins from mastectomy pathology (no invasive cells at margin) • 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 • Radiation oncologist intends to treat all target volumes and respect all normal tissues in accordance with the dosimetric constraints described (simulation before registration recommended) • Radiation oncologist is planning to treat regional lymph nodes including internal mammary nodes and meet acceptable protocol dosimetric requirements • Radiation oncologist is NOT planning to utilize a chest wall/scar boost • Patient must have undergone immediate reconstruction at the time of mastectomy or be planning to undergo reconstruction within 8 months after radiation • For patients with diabetes, hemoglobin A1C test must have been performed =< 90 days prior to registration • No co-existing medical conditions with life expectancy < 5 years • 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 • Negative serum or urine beta-human chorionic gonadotropin (HCG) in women of child-bearing potential =< 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 • Women of child-bearing potential must agree to utilize a form of birth control or agree to undergo sexual abstinence during radiation therapy • Eastern Cooperative Oncology Group (ECOG) (Zubrod) performance status 0-1
Critères d'exclusion	