Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Multi-institution Phase II Trial of Intraoperative Electron Beam Radiotherapy Boost at the Time of Breast Conserving Surgery With Oncoplastic Reconstruction in Women With Early-Stage Breast Cancer
Protocole ID	OSU-16106
ClinicalTrials.gov ID	NCT02927912
Type(s) de cancer	Sein
Phase	Phase II
Type étude	Clinique
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Rami Younan
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Statut	Fermé
But étude	This phase II trial studies the side effects of intraoperative electron beam radiotherapy boost and to see how well it works in treating patients with stage I-II breast cancer undergoing surgery with reconstruction. Giving a single dose of electron beam radiation to the tumor cavity during the breast surgery before reconstruction may be a better way to kill tumor cells and shrink tumors.
Critères d'éligibilité	• Pathologically proven diagnosis of breast cancer • Clinical node negative stage I (T1N0) or stage II (T2N0) breast cancer • Preoperative ultrasound of the axilla with biopsy of suspicious nodes is recommended as clinically indicated per the discretion of the treating physician • Appropriate stage for protocol entry including no clinical evidence for distant metastases based upon the following minimum diagnostic workup • History/physical examination, documentation of weight and Zubrod performance status 0-2 within 28 days prior to study entry • Right and left mammography within 90 days of diagnostic biopsy establishing diagnosis • Absolute neutrophil count > 1800 cells/cubic mm • Platelets >= 75,000 cells/cubic mm • Hemoglobin >= 8 g/dL • Women of childbearing potential must have a negative urine or serum pregnancy test within 14 days of study entry • Women of childbearing potential must be non-pregnant and non-lactating and willing to use medically acceptable form of contraception during radiation therapy • Patients must provide study specific informed consent prior to study entry
Critères d'exclusion	• Clinical T4, N2 or N3, M1 pathologic stages III or IV breast cancer • Prior invasive non-breast malignancy (except non-melanoma skin cancer, carcinoma in situ of the cervix) unless disease free for a minimum of 3 yrs prior to study entry • Prior invasive or in-situ carcinoma of the breast (prior lobular breast carcinoma in situ [LCIS] is eligible) • Two or more cancers not resectable through a single lumpectomy incision • Bilateral breast cancer • Ductal breast carcinoma in situ (DCIS) only • Non-epithelial breast malignancies such as sarcoma/lymphoma • Male breast cancer • Paget's disease of the nipple • Prior radiotherapy to the breast or prior radiation to the region of the ipsilateral breast that would result in overlap of radiation fields

- Pregnancy or women of childbearing potential who are sexually active and not willing/able to use medically acceptable forms of contraception
- Active systemic lupus, erythematosus, or any history of scleroderma, dermatomyositis with active rash
- Medical, psychiatric or other condition that would prevent the patient from receiving the protocol therapy or providing informed consent