Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Essai randomisé portant sur la radiothérapie régionale pour le traitement du cancer du sein avec envahissement ganglionnaire à faible risque avec biomarqueur.
Protocole ID	MA.39
ClinicalTrials.gov ID	NCT03488693
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Traitement
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Pierre Rousseau
Coordonnateur	Diane Trudel 514-890-8000 poste 11181
Statut	Actif en recrutement
But étude	The purpose of this study is to compare the effects on low risk breast cancer receiving usual care that includes regional radiation therapy, with receiving no regional radiation therapy. Researchers want to see if not giving this type of radiation treatment works as well at preventing breast cancer from coming back.
Critères d'éligibilité	• Patients must have newly diagnosed histologically proven invasive carcinoma of the breast with no evidence of metastases. • Patients must have been treated by BCS or mastectomy. • Patients treated by BCS or mastectomy and axillary dissection must have 1-3 positive axillary nodes (macrometastases, > 2 mm). • Patients treated by BCS and SLNB alone must have only 1-2 positive axillary nodes (macrometastases, > 2 mm). • Patients treated by mastectomy and SLNB alone must have only 1 positive axillary node (macrometastases, > 2 mm). • Patients must be ER ≥ 1% and HER2 negative on local testing • Patients must have an Oncotype DX recurrence score <18 • Patient must consent to provision of, and investigator(s) must confirm access to and agree to submit to the CCTG Central Tumour Bank, a representative formalin fixed paraffin block of tumour tissue in order that the specific correlative marker assays described in the protocol may be conducted • Patient must consent to provision of samples of blood in order that the specific correlative marker assays described in the protocol may be conducted. • Patients must have had endocrine therapy initiated or planned for ≥ 5 years. Endocrine therapy can be given concurrently or following RT. • Patients may or may not have had adjuvant chemotherapy. • RT must be administered within 12 weeks of definitive surgery if the patient is not treated with chemotherapy. If adjuvant chemotherapy is given, RT must begin within 2-8 weeks after the last dose. • Patient's ECOG performance status must be 0, 1 or 2. • Patient's age must be ≥ 40 years. • Patient's life expectancy is ≥10 years • For the first 736 eligible English or French-speaking subjects who have agreed to optional questionnaire completion: Patient is able (i.e. sufficiently fluent) and willing to complete the quality of life, health utilities and lost productivity questionnaires in either English or French • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements • Patients must be accessible for treatment and follow-up. Investigators must assure themselves

	the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up. • In accordance with CCTG policy, protocol treatment is to begin within 3 weeks of patient randomization. • Women of childbearing potential must have agreed to use an effective contraceptive method. A woman is considered to be of "childbearing potential" if she has had menses at any time in the preceding 12 consecutive months.
Critères d'exclusion	• Patients with nodal disease limited to micrometastases (pN1Mi, > 0.2 mm and ≤ 2 mm) or isolated tumour cells (pN0i+ < 0.2 mm). • Any prior history, not including the index cancer, of ipsilateral invasive breast cancer or ipsilateral DCIS treated with radiation therapy. (Patients with synchronous or previous ipsilateral LCIS are eligible.) • Synchronous or previous contralateral invasive breast cancer. (Patients with contralateral DCIS not treated with radiation are eligible.) • History of non-breast malignancies except adequately treated non-melanoma skin cancers, in situ cancers treated by local excision or other cancers curatively treated with no evidence of disease for ≥ 5 years. • Patients with pT3 or pT4 disease. • Patients who are pregnant. • Patients that have had prior ipsilateral chestwall/thoracic radiation. • Patients treated with neoadjuvant chemo or endocrine therapy for breast cancer. • Patients with serious non-malignant disease (e.g. cardiovascular, scleroderma etc.) which would preclude RT. • Patients with any serious active or co-morbid medical conditions, laboratory abnormality, psychiatric illness, active or uncontrolled infections, or serious illnesses or medical conditions that would prevent the patient from participating or to be managed according to the protocol (according to investigator's decision).