Essai Clinique

Généré le 21 mai 2024 à partir de

Titre	Prospective Evaluation of Breast-Conserving Surgery Alone in Low-Risk Ductal Carcinoma in Situ Defined by a Molecular Expression Assay Combined With Clinico-Pathological Features
Protocole ID	ELISA
ClinicalTrials.gov ID	NCT04797299
Type(s) de cancer	Sein
Phase	Autres
Type étude	Autre
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	
Investigateur principal	Dre Nancy El-Bared
Coordonnateur	Caroline Hivon 450-466-5000 poste 2164
Statut	Actif en recrutement
But étude	A prospective cohort study, conducted in Canada, to prospectively evaluate whether the combination of clinicopathological criteria and the Oncotype DX DCIS score can identify a group of women at very low risk of local recurrence following breast conserving surgery who do not require breast radiation therapy. We plan to screen 809 consenting women who will have their tumour tissue specimen sent to Exact Sciences to assess their DCIS score. We anticipate that 526 women will have an Oncotype DX DCIS score <39 and a predicted 10-year risk of local recurrence <10%, these patients will be enrolled and followed as part of the study. At each centre, all patients with DCIS referred to radiation oncology will be documented. When a physician identifies an eligible patient, the patient will be approached by the referring physician or delegate to voluntarily provide informed consent to participate in this study. Consenting patients will be registered through the Ontario Clinical Oncology Group's (OCOG) web-based registration system. A two-step registration/enrollment process will be implemented. Data related to the patient demographics, surgery details, tumour characteristics and ECOG performance will be collected. The patient's tumour specimen will be sent for analysis to Exact Sciences. The DCIS score results will be sent to the referring physician. OCOG will also receive the DCIS score results. Patients will be followed every 6 months for the first 2 years and then yearly up to 10 years. Bilateral mammograms will be performed 6 months after BCS and then annually. The study data will be verified by source documentation.
Critères d'éligibilité	• Female patient > 45 years of age with DCIS without microinvasion. • Tumour size ≤ 2.5cm. • Treated by BCS with clear resection margins ≥ 2 mm or no residual disease on re-excision. • Oncotype DX DCIS score < 39 and predicted 10-year risk of LR <10%.
Critères d'exclusion	• Multifocal DCIS. • History of any invasive breast cancer or non-invasive breast cancer in the ipsilateral breast. • Synchronous or previous invasive or non-invasive breast cancer. • Prior history of invasive cancer within the last 5 years, excluding non-melanoma skin cancers. • ECOG performance status ≥3. • Life expectancy <10 years. • Geographic inaccessibility for follow-up. • Inability to provide informed consent.