Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	Sentinel Node Biopsy and Targeted Axillary Dissection in Node-Positive Breast Cancer Patients With Clinically Negative Axilla
Protocole ID	TADEN
ClinicalTrials.gov ID	NCT04671511
Type(s) de cancer	Sein
Phase	Autres
Type étude	Clinique
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Jean-François Boileau
Coordonnateur	Joelle-Marie Poirier 514-340-8222 poste 23766
Statut	Actif en recrutement
But étude	RATIONALE: It is now standard for most breast cancer patients with 1-2 positive sentinel nodes to avoid completion node dissection when eligibility criteria from the American College of Surgeons Oncology Group (ACOSOG) Z0011 trial are met. The National Comprehensive Cancer Network (NCCN) recently proposed to extend this indication to patients that present with biopsy proven node positive disease if only 1 or 2 suspicious nodes are found on imaging, these positive nodes are not palpable clinically, and the other eligibility criteria from the Z0011 study are otherwise met. However, this recommendation is based on an expert consensus and no study has yet confirmed the optimal method to stage the axilla in this patient popula PURPOSE: Evaluate the technical success rate and accuracy of sentinel node biopsy (SNB) and the potential benefits of clipping and removing the biopsy proven node using radioactive seed localisation (RSL) (SNB+RSL = Targeted Axillary Dissection (TAD)) in patients with biopsy proven positive nodes, limited nodal disease in imaging and clinically negative axillary examination.
Critères d'éligibilité	• Participants must be ≥ 18 years old. • Participants with a clinical T1 or T2 invasive ductal or lobular breast carcinoma, regardless of estrogen/progesterone/human epidermal growth factor receptor 2 (HER2) receptor status. • Participants with clinical (on palpation) N0 and up to two suspicious lymph nodes on axillary ultrasound. • Participant with biopsy-proven positive axillary disease made by core needle biopsy or fine-needle aspiration. • Participants must have an Eastern Cooperative Oncology Group (ECOG) Scale of Performance Status less than 2. • Participants must understand, accept, and have signed the approved consent form.
Critères d'exclusion	• Participant with previous ipsilateral axillary surgery, including sentinel lymph node biopsy. • Participants with distant metastases. • Participants that have had previous radiotherapy to the axillary nodes. • Participants who received neoadjuvant therapy. • If the injection of blue dye is planned, patients with hypersensitivity or allergy to isosulfan blue, patent blue, methylene blue or radiocolloid dye. • Participants who are unable to provide informed consent.