Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Prevention of Persistent Pain With LidocAine iNfusions in Breast Cancer Surgery
Protocole ID	PLAN
ClinicalTrials.gov ID	NCT04874038
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dr Philippe Richebé
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Statut	Actif en recrutement
But étude	Phase III, international multicentre, parallel group, blinded, 1:1 randomized controlled trial to determine the effect of an intraoperative intravenous lidocaine infusion on reducing the development of persistent pain 3-months after breast cancer surgery. PLAN is a multicentre, parallel-group, blinded, randomized controlled trial of 1,150 patients undergoing breast cancer surgery. Consented eligible patients will be randomized to receive an intravenous lidocaine: 1.5 mg/kg bolus with induction of general anesthesia followed by a 2.0 mg/kg/hour infusion until the end of surgery (and up to 30 minutes into recovery room). Patients in the control group will receive a placebo bolus and infusion with normal saline (0.9% sodium chloride solution). Study medications will be prepared in blinded 50 mL syringes and labelled as per Regulatory requirements. Patients will follow up on the first 3 days after surgery, and at 3 and 12-months postoperatively to report on pain, analgesic consumption, functional, mood, and quality of life outcomes
Critères d'éligibilité	• Age ≥18 years old • Undergoing a unilateral or bilateral lumpectomy or mastectomy, inclusive of all pathologies, including prophylactic surgery (e.g., family history or BRCA gene mutation)
Critères d'exclusion	• Previous breast surgery within 6 months of index surgery • Undergoing any autologous flap procedure during index surgery • Presence known chronic pain disorder involving surgical site or ipsilateral chest wall, shoulder, or arm during the 3-months prior to index surgery • Documented hypersensitivity or allergy to lidocaine • Surgery not planned to be performed under general anesthesia and/or planned use of regional or neuraxial anesthetic techniques before surgery (i.e., epidural, paravertebral, serratus plane block, pectoralis or modified pectoralis block) • History of ventricular tachycardia, ventricular fibrillation, or atrioventricular block without a pacemaker • Known cirrhotic liver disease • Pregnant • Unlikely to comply with follow-up (e.g. no fixed address, language difficulties that would impede valid completion of questionnaires, plans to move out of town)