



Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Randomized Controlled Trial of Endoscopic Ultrasound Guided Celiac Plexus Neurolysis (EUS-CPN) With and Without Bupivacaine
Protocole ID	21.151
ClinicalTrials.gov ID	NCT04951804
Type(s) de cancer	Pancréas
Phase	Autres
Type étude	Clinique
Médicament	Neurolyse du plexus coélique guidé par échographie endoscopique avec ou sans bupivacaine
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Anand Sahai
Coordonnateur	Charles Mackay 514-890-8000 poste 36484
Statut	Actif en recrutement
Date d'activation	01-08-2022
But étude	<p>Endoscopic ultrasound (EUS) allows EUS-guided trans gastric injection of absolute alcohol around the base of the celiac plexus (celiac plexus neurolysis (EUS-CPN)), to help alleviate pain associated with pancreatic cancer. It is standard procedure to inject bupivacaine immediately before injecting absolute alcohol, to theoretically prevent pain that may occur during and after the procedure. However, there are no data showing whether bupivacaine injection has any real influence on intra-procedural, immediate post-procedural, or long-term pain control. The injection of bupivacaine before the alcohol may have no effect, a synergistic effect, or an antagonistic effect, by diluting the alcohol, and reducing its neurolytic capacity. Inadvertent intravascular injection of bupivacaine may also cause irreversible cardiac arrhythmias and death. The investigators therefore propose a randomized clinical trial to determine whether the exclusion of bupivacaine during EUS-guided CPN improves outcomes, or not.</p>
Critères d'éligibilité	<ul style="list-style-type: none">• Malignant-appearing pancreatic mass, or proven pancreatic cancer involving the pancreatic genu, body, or tail• Any level of abdominal or back pain considered to be potentially related to the mass:<ul style="list-style-type: none">• New onset pain (<3 months)• Constant• Centrally located• With or without irradiation to the back• No obvious other source of pain based on history and physical examination by the attending endosonographer• No possibility of surgical management• Signed, informed consent• Celiac axis accessible for bilateral neurolysis at EUS.
Critères d'exclusion	<ul style="list-style-type: none">• Allergy to bupivacaine