Essai Clinique

Généré le 21 juin 2024 à partir de

Titre	Étude internationale de validation de la biopsie du ganglion sentinelle dans le cancer du col de l'utérus au stade précoce
Protocole ID	SENTICOL III
ClinicalTrials.gov ID	NCT03386734
Type(s) de cancer	Col
Phase	Autres
Type étude	Clinique
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Vanessa Samouëlian
Coordonnateur	France Gauthier 514-890-8000 poste 30921
Statut	Actif en recrutement
But étude	SENTICOL III is large prospective multicenter international randomized study designed to validate the Sentinel Lymph Node (SLN) mapping technique in early cervical cancer. This "validation study" will compare the outcome of patients with negative SLN (experimental arm) vs patients with negative SLN + Pelvic Lymph Node dissection (PLN)(reference arm). There will be a "quality assurance" program which will be developed in participating centers with detailed requirements in terms of surgeons' qualifications, pathology qualification, SLN ultrastaging, standardization of the procedure, etc. as well as respect of the "safety algorithm".
Critères d'éligibilité	• With squamous or adenocarcinoma of the cervix (proven by biopsy or cone biopsy), • Stage Ia1 with lymphovascular emboli, Ia2, Ib1 and IIa1 (clinical stage) of the 2009 FIGO classification, • Maximum diameter ≤ 40 mm by clinical examination and magnetic resonance imaging (MRI), • INo suspicious node on pelvic and abdominal MRI with an exploration up to the femoralleft renal vein (according to RECIST 1.1), • Eastern Cooperative Oncology Group (ECOG) Performance status 0-2, • Signed informed consent and ability to comply with follow-up,
Critères d'exclusion	• Pregnancy, • Previous pelvic or abdominal cancer, • Previous chemotherapy and/or radiation therapy for the cervical cancer (previous brachytherapy is accepted), • Proven allergy to blue dye, isotope or indocyanine green (ICG).