Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Randomized Controlled Trial of Robotic Versus Open Surgery for Early Stage Cervical Cancer (ROCC)
Protocole ID	ROCC (GOG-3043)
ClinicalTrials.gov ID	NCT04831580
Type(s) de cancer	Col
Phase	Autres
Type étude	Traitement
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Vanessa Samouëlian
Coordonnateur	
Statut	Actif en recrutement
Date d'activation	20-06-2024
But étude	This is a randomized controlled trial to compare survival for patients who undergoe robotic assisted laparoscopy versus open hysterectomy and lymph node assessment for the treatment of early stage cervical cancer.

Critères d'éligibilité	• Patient must have histologically confirmed adenocarcinoma (usual/classic/NOS), squamous cell carcinoma, adenosquamous carcinoma (Including glassy cell)
	• Patient must be FIGO Stage IA2, IBI, IB2 (2018 staging) without evidence of definitive parametrial, vaginal, nodal or distant metastases on exam or imaging. Patients with tumor size less than or equal to 4 cm confirmed on MRI prior to randomization are eligible.
	• Patient must have uterine size <12 cm AND felt to be appropriate for vaginal delivery of the specimen per investigator.
	• Patient must be suitable surgical candidate with preoperative assessments such as labs and EKG performed per institutional standard and agree to be randomized to undergo open or robotic radical (or simple) hysterectomy. NOTE: Simple hysterectomy will be allowed in patients who meet the following criteria: Submission of source documents in the GOG Partners Source Document Portal will be required prior to randomization for review and confirmation of simple hysterectomy being met (see Section 6.0 for instructions).
	  • pelvic MRI must demonstrate a maximal tumor size of 2 cm or less AND
	  • less than 50% stromal invasion on MRI if tumor present or less than 10 mm of stromal invasion if an excisional (cold knife or LEEP) has been performed.
	• Patient must be age 18 years or older.
	• Patient must have ECOG performance status 0-1.
	• Patient must have a negative urine pregnancy test within 30 days of surgery in pre-menopausal women.
	• Patient must have signed an approved informed consent and authorization permitting the release of personal health information.

Critères d'exclusion	• Patients with any tumor histology other than those listed above, specifically excluding the following histologies: neuroendocrine, other adenocarcinoma (gastric type, endometrioid, clear cell, serous, signet ring, minimal deviation) • Patients with FIGO stage 1A1, IB3, II-IV (2018 staging). • Patient with inability to receive an MRI. • Patients with a tumor size greater than 4cm or on MRI confirmed prior to randomization are excluded. Patients with definite evidence of vaginal/parametrial involvement on MRI are

excluded; if MRI findings are not definitive, then clinical examination must also not reveal parametrial or vaginal extension).
- Patients with evidence of metastatic disease (imaging or histologically positive lymph nodes).
- Patients with a history of prior pelvic or abdominal radiotherapy.
- Patients with a prior malignancy < 5 years from enrollment with the exception of non-melanoma skin cancer.
- Patients who are unable to withstand prolonged lithotomy or steep trendelenberg.
- Patient compliance and geographic proximity that do not allow adequate follow-up.
- Patients with poorly controlled HIV with CD4 counts <500.