Essai Clinique

Généré le 18 avr. 2024 à partir de

Titre	Étude randomisée de phase III portant sur l'association chimiothérapie-radiothérapie pelvienne avec ou sans chimiothérapie adjuvante chez des patientes atteintes d'un carcinome du col de l'utérus de stade précoce à risque élevé après une hystérectomie radicale
Protocole ID	RTOG 0724
ClinicalTrials.gov ID	NCT00980954
Type(s) de cancer	Col
Phase	Phase III
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1 (Étude du programme d'oncologie de McGill)
Ville	Montréal
Investigateur principal	Dr Luis Souhami
Coordonnateur	Ginette Ricard 514-934-1934 poste 43186
Statut	Actif en recrutement
But étude	This randomized phase III trial is studying chemotherapy and pelvic radiation therapy to see how well they work when given with or without additional chemotherapy in treating patients with high-risk early-stage cervical cancer after radical hysterectomy.

Critères d'éligibilité	DISEASE CHARACTERISTICS:
	• Histologically confirmed squamous, adenosquamous, or adenocarcinoma of the cervix with any/all of the following high-risk features after surgery:
	  • Positive pelvic nodes
	  • Positive parametrium
	  • Positive para-aortic nodes that have been completely resected and are PET/CT scan-negative
	• Clinical stage IA2, IB, or IIA disease (this corresponds to surgical TNM staging of T1-T2, N1, M0)
	• Must have undergone radical hysterectomy (open, laparoscopically, or robotic) and staging within the past 70 days
	  • Para-aortic and pelvic node sampling required
	  • No gross residual disease
	• No neuroendocrine histology
	• No distant metastases
	
	PATIENT CHARACTERISTICS:
	• Zubrod performance status 0-1
	• ANC ≥ 1,800/mm³
	• Platelets ≥ 100,000/mm³
	• WBC ≥ 4,000/mm³
	• Hemoglobin ≥ 10.0 g/dL (transfusion or other intervention allowed)
	• Serum creatinine ≤ 1.5 mg/dL
	• Bilirubin ≤ 1.5 times upper limit of normal
	• ALT and/or AST normal
	• Alkaline phosphatase normal
	• Known HIV positivity allowed provided CD4 count is ≥ 350/mm³ within the past 14 days
	• No other invasive malignancy within the past 3 years, except nonmelanomatous skin cancer or carcinoma in situ of the breast, oral cavity, or cervix
	• No severe, active co-morbidity, including any of the following:
	  • Unstable angina and/or congestive heart failure requiring hospitalization within the past 6 months

	• Transmural myocardial infarction within the past 6 months • Acute bacterial or fungal infection requiring IV antibiotics at the time of study entry • Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of study entry • Coagulation defects • No prior allergic reaction to carboplatin, paclitaxel, and/or cisplatin PRIOR CONCURRENT THERAPY: • See Disease Characteristics • No prior systemic chemotherapy for the current cervical cancer • Prior chemotherapy for a different cancer is allowed • No prior radiotherapy to the pelvis that would result in overlap of radiotherapy fields
Critères d'exclusion	