Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	Étude randomisée de phase III chez les patientes avec cancers de l'endomètre avancés après cytoréduction optimale pour comparer la radiothérapie pelvienne avec cisplatine concomitant suivi de carboplatine et paclitaxel versus le traitement sandwich de carboplatine et paclitaxel puis radiothérapie pelvienne et reprise de carboplatine et paclitaxel.
Protocole ID	LUNCHBOX
ClinicalTrials.gov ID	NCT02501954
Type(s) de cancer	Endomètre
Phase	Phase III
Type étude	Traitement
Médicament	carboplatine et paclitaxel
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dre Béatrice Cormier
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Statut	Fermé
Date d'activation	10-10-2017
But étude	To determine if treatment with cisplatin and radiation followed by carbo and taxol reduces the rate of recurrence when compared to sandwich therapy.
Critères d'éligibilité	• All patients with Surgical Stage III or IVA endometrial carcinoma per FIGO 2009 staging criteria, including clear cell and serous papillary and undifferentiated carcinomas. • Surgical Stage III disease includes those patients with positive adnexa, parametrial involvement, tumor invading the serosa, positive pelvic and/or para-aortic nodes, or vaginal involvement. • Surgical Stage IVA includes patients with bladder or bowel mucosal involvement, but no spread outside the pelvis. • Patients with FIGO 2009 surgical Stage I or II endometrial clear cell or serous carcinoma and with positive peritoneal cytology. • Surgery must have included a hysterectomy and bilateral salpingooophorectomy. Pelvic lymph node sampling and para-aortic lymph node sampling are optional. • Patients with a GOG Performance Status of 0, 1, or 2. • Patients with adequate organ function, reflected by the following parameters: • WBC ≥ 3000/mcl • Absolute neutrophil count (ANC) ≥ 1500/mcl • Platelet count ≥ 100,000/mcl • SGOT, SGPT, and alkaline phosphatase ≤ 2.5 X upper limit of normal (ULN) • Bilirubin ≤ 1.5 X ULN • Creatinine ≤ institutional ULN • Patients must be 18 years of age or older. • Entry into the study is limited to no more than 8 weeks from the date of surgery. All patients with Surgical Stage III or IVA endometrial carcinoma per FIGO 2009 staging criteria, including clear cell and serous papillary and undifferentiated carcinomas. Surgical Stage III disease includes those patients with positive adnexa, parametrial involvement, tumor invading the serosa, positive pelvic and/or para-aortic nodes, or vaginal involvement. Surgical Stage IVA includes patients with bladder or bowel mucosal involvement, but no spread outside

	the pelvis. Patients with FIGO 2009 surgical Stage I or II endometrial clear cell or serous carcinoma and with positive peritoneal cytology. Surgery must have included a hysterectomy and bilateral salpingooophorectomy. Pelvic lymph node sampling and para-aortic lymph node sampling are optional. Patients with a GOG Performance Status of 0, 1, or 2. Patients with adequate organ function, reflected by the following parameters: WBC ≥ 3000/mcl Absolute neutrophil count (ANC) ≥ 1500/mcl Platelet count ≥ 100,000/mcl SGOT, SGPT, and alkaline phosphatase ≤ 2.5 X upper limit of normal (ULN) Bilirubin ≤ 1.5 X ULN Creatinine ≤ institutional ULN Patients must be 18 years of age or older. Entry into the study is limited to no more than 8 weeks from the date of surgery.
Critères d'exclusion	• Patients with carcinosarcoma. • Patients with recurrent endometrial cancer. • Patients with residual tumor after surgery (any single site) exceeding 1 cm in maximum dimension. • Patients who have had pelvic or abdominal radiation therapy. • Patients with positive pelvic washings as the only extra-uterine disease are NOT eligible if the histology is other than clear cell or papillary serous carcinoma. • Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are excluded if there is any evidence of active malignancy within the last five years. Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy. • Patients with a history of serious co-morbid illness or uncontrolled illnesses that would preclude protocol therapy. • Patients with an estimated survival of less than three months. • Patients with FIGO 2009 Stage IVB endometrial cancer. • Patients with parenchymal liver metastases. • Patients who have received prior chemotherapy for endometrial cancer. • Patients with a history of myocardial infarction, unstable angina, or uncontrolled arrhythmia within 3 months from enrollment.