Essai Clinique

Généré le 09 déc. 2024 à partir de

Titre	Une étude de phase I-II évaluant la radiothérapie préopératoire en une seule fraction pour les femmes atteintes d'un cancer du sein de stade précoce
Protocole ID	SPORT DS
ClinicalTrials.gov ID	
Type(s) de cancer	Sein
Phase	Phase I-II
Médicament	aucun
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dr Michael Yassa
Coordonnateur	Véronique Tran 514-252-3400 poste 3227
Statut	Actif en recrutement
But étude	The primary study endpoint is The rate of pathological complete response (pCR) as assessed by microscopic evaluation of the surgical specimen
Critères d'éligibilité	• Female aged 65 years or older • World Health Organization (WHO) performance status 0-2 • Invasive ductal carcinoma proven by biopsy done ≤ 12 weeks from treatment start • Unifocal disease on preoperative staging ultrasound done ≤ 12 weeks from treatment start • Tumors less than 2cm clinically on physical exam, as well as on breast ultrasound • No clinical evidence of nodal disease (i.e. cN0), on physical examination done ≤ 12 weeks from treatment start, as well as on breast ultrasound • Estrogen receptor status (ER) positive on biopsy • Her2 negative on biopsy • Grade 1 or 2 on biopsy • Planned surgery is a partial mastectomy with sentinel lymph node biopsy • Localisation markers placed before treatment
Critères d'exclusion	• Age less than 65 years • A known deleterious mutation in BRCA 1 and/or BRCA 2 • Clinical tumor size > 2.0 cm in greatest diameter on staging ultrasound • Tumor histology limited to lobular carcinoma only • Clinically positive axillary nodes (cN+) • Lymphovascular invasion on biopsy • Pure ductal or lobular carcinoma in situ on biopsy • Extensive intraductal component on biopsy • Neoadjuvant hormonal manipulation or chemotherapy • Prior history of cancer (Patients with prior or concurrent basal cell or squamous cell skin cancers are eligible for the trial) • More than one primary tumor in different quadrants of the same breast • Diffuse microcalcifications on mammography • Paget's disease of the nipple • Previous irradiation to the ipsilateral breast • Presence of an ipsilateral breast implant or pacemaker • Serious non-malignant disease (e.g. cardiovascular, pulmonary, systemic lupus erythematosus (SLE), scleroderma) which would preclude definitive radiation treatment

- Estrogen receptor status (ER) not known
- Currently pregnant or lactating
- Psychiatric or addictive disorders which would preclude obtaining informed consent or adherence to protocol
- Geographic inaccessibility for follow-up
- Lack of preoperative staging with breast and axillary ultrasound
- Inability to adequately plan the patient for the experimental technique