Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Randomized Trial of Five-Fraction Partial Breast Irradiation
Protocole ID	RAPID2
ClinicalTrials.gov ID	NCT05417516
Type(s) de cancer	Sein
Type étude	Clinique
Médicament	Radiothérapie
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Tarek Hijal
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Statut	Actif en recrutement
Date d'activation	16-01-2024
But étude	The primary objective of this study is to determine in women with node negative BC ≤3cm in size, if PBI compared to WBI, both given once-a-day over 1 week following BCS, is non-inferior for LR and reduces adverse cosmesis. The primary outcomes are LR and patient-assessed cosmesis at 3 years post randomization.
Critères d'éligibilité	• Female with a new histological diagnosis of invasive carcinoma of the breast with no evidence of metastatic disease.(AJCC TNM Cancer Staging). • Treated by BCS with microscopically clear resection margins ≥ 1mm for invasive and non-invasive disease or no residual disease on re-excision. • Negative axillary node involvement as determined by either sentinel lymph node biopsy or axillary node dissection.
Critères d'exclusion	• Age less than 50 years. • Known to be BRCA 1 and/or BRCA 2 positive. • Tumour size >3cm in greatest diameter on pathological examination. • Lobular carcinoma only. • More than one primary tumour in different quadrants of the same breast (patients with multifocal breast cancer are eligible). • Synchronous or previous contralateral breast cancer (patients with contralateral DCIS or LCIS are eligible). • History of non-breast malignancy within the last 5 years other than treated non-melanoma skin cancer or treated in-situ carcinoma. • Known pregnancy or currently lactating. • Inability to localize tumour bed on CT planning (no evidence of surgical clips or seroma). • Inability to plan the patient for the experimental technique.