

## Essai Clinique Généré le 27 avr. 2025 à partir de

Titre	A Randomized Trial of Five-Fraction Partial Breast Irradiation
Protocole ID	RAPID2
ClinicalTrials.gov ID	<u>NCT05417516</u>
Type(s) de cancer	Sein
Type étude	Clinique
Médicament	Radiothérapie
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dre Valérie Théberge
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Statut	Actif en recrutement
Date d'activation	18-10-2023
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	<ul> <li>Female with a new histological diagnosis of invasive carcinoma of the breast with no evidence of metastatic disease.(AJCC TNM Cancer Staging).</li> <li>Treated by BCS with microscopically clear resection margins ≥ 1mm for invasive and non-invasive disease or no residual disease on re-excision.</li> <li>Negative axillary node involvement as determined by either sentinel lymph node biopsy or axillary node dissection.</li> </ul>
Critères d'exclusion	<ul> <li>Age less than 50 years.</li> <li>Known to be BRCA 1 and/or BRCA 2 positive.</li> <li>Tumour size &gt;3cm in greatest diameter on pathological examination.</li> <li>Lobular carcinoma only.</li> <li>More than one primary tumour in different quadrants of the same breast (patients with multifocal breast cancer are eligible).</li> <li>Synchronous or previous contralateral breast cancer (patients with contralateral DCIS or LCIS are eligible).</li> <li>History of non-breast malignancy within the last 5 years other than treated non-melanoma skin cancer or treated in-situ carcinoma.</li> <li>Known pregnancy or currently lactating.</li> <li>Inability to localize tumour bed on CT planning (no evidence of surgical clips or seroma).</li> <li>Inability to plan the patient for the experimental technique.</li> </ul>