Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	A Randomized Phase III Trial of Stereotactic Ablative Radiotherapy for the Comprehensive Treatment of 4-10 Oligometastatic Tumors
Protocole ID	SABR-COMET 10
ClinicalTrials.gov ID	NCT03721341
Type(s) de cancer	Tumeurs solides
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Médicament	Radiothérapie ablative
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
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Statut	Fermé
But étude	In patients with a limited oligometastatic burden (cancer has spread but is not yet considered metastatic), emerging evidence suggests that treatment of all sites of disease with ablative therapies can improve patient outcomes, including overall- and progression-free survival. The application of Stereotactic Ablative Radiotherapy (SABR) for patients with 4-10 metastatic deposits appears promising, yet it is unclear if all patients with greater than 3 oligometastatic lesions benefit from ablative therapies in terms of improved Overall Survival (OS), Progression Free Survival (PFS), or quality of life. The purpose of this study is to assess the impact of SABR, compared to standard of care treatment, on overall survival, oncologic outcomes, and quality of life in patients with a controlled primary tumor and 4-10 metastatic lesions.
Critères d'éligibilité	• Age 18 or older • Willing to provide informed consent • Karnofsky performance score greater than 60 • Life expectancy greater than 6 months • Histologically confirmed malignancy with metastatic disease detected on imaging. Biopsy of metastasis is preferred, but not required. • Controlled primary tumor defined as: at least 3 months since original tumor treated definitively, with no progression at primary site • Total number of metastases 4-10 • All sites of disease can be safely treated based on a pre-plan
Critères d'exclusion	• Serious medical comorbidities precluding radiotherapy. These include interstitial lung disease in patients requiring thoracic radiation, Crohn's disease in patients where the GI tract will receive radiotherapy, and connective tissue disorders such as lupus or scleroderma. • For patients with liver metastases, moderate/severe liver dysfunction (Child Pugh B or C) • Substantial overlap with a previously treated radiation volume. Prior radiotherapy in general is allowed, as long as the composite plan meets dose constraints herein. For patients treated with radiation previously, biological effective dose calculations should be used to equate previous doses to the tolerance doses listed below. All such cases must be discussed with one of the study PIs.

- Malignant pleural effusion
- Inability to treat all sites of disease
- Any single metastasis greater than 5 cm in size.
- Any brain metastasis greater than 3 cm in size or a total volume of brain metastases greater than 30 cc.
- Metastasis in the brainstem
- Clinical or radiologic evidence of spinal cord compression
- Dominant brain metastasis requiring surgical decompression
- Metastatic disease that invades any of the following: GI tract (including esophagus, stomach, small or large bowel), mesenteric lymph nodes, or skin
- Pregnant or lactating women