Essai Clinique

Généré le 19 mai 2025 à partir de

Titre	Un essai de phase III comparant la radiochirurgie stéréotaxique à la radiothérapie du cerveau entier pour le traitement de 5 à 15 métastases cérébrales
Protocole ID	CE.7
ClinicalTrials.gov ID	NCT03550391
Type(s) de cancer	Cerveau (SNC)
Phase	Phase III
Type étude	Traitement
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
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Statut	Actif en recrutement
But étude	Stereotactic radiosurgery (SRS) is a commonly used treatment for brain tumors. It is a one-day (or in some cases two day), out-patient procedure during which a high dose of radiation is delivered to small spots in the brain while excluding the surrounding normal brain. Whole brain radiation therapy (WBRT) is when radiation therapy is given to the whole brain. Memantine is a drug that is given to help relieve symptoms that can be caused by WBRT, including problems with memory and other mental symptoms. Health Canada, the regulatory body that oversees the use of drugs in Canada, has not approved the sale or use of memantine in combination with WBRT to treat this kind of cancer, although they have allowed its use in this study.
Critères d'éligibilité	• Patients must have 5 or more brain metastases as counted on a T1 contrast enhanced MRI obtained ≤ 30 days from randomization (maximum 15 brain metastases). • Patients must have a pathological diagnosis (cytological or histological) of a non-hematopoietic malignancy. • The largest brain metastasis must measure <2.5 cm in maximal diameter. • Centre must have the ability to treat patients with either a Gamma Knife, Cyberknife, or a linear accelerator-based radiosurgery system. • Patient must be > 18 years of age. • Patient is able (i.e. sufficiently fluent) and willing to complete the quality of life questionnaires in either English or French either alone or with assistance. • ECOG performance status 0, 1, or 2. • Creatinine clearance must be ≥ 30 ml/min within 28 days prior to registration. • The Neurocognitive Testing examiner must have credentialing confirming completion of the neurocognitive testing training. • Facility is credentialed by IROC to perform SRS. The treating centre must have completed stereotactic radiosurgery credentialing of the specific system(s) to be used in study patients. • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrolment in the trial to document their willingness to participate. • A similar process must be followed for sites outside of Canada as per their respective cooperative group's procedures. • Patients must be accessible for treatment and follow-up. Investigators must assure themselves the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up. • In accordance with CCTG policy, protocol treatment is to begin within 14 days of patient enrolment.

	• Women/men of childbearing potential must have agreed to use a highly effective contraceptive method.
Critères d'exclusion	• Pregnant or nursing women. • Men or women of childbearing potential who are unwilling to employ adequate contraception. • Inability to complete a brain MRI. • Known allergy to gadolinium. • Prior cranial radiation therapy. • Planned cytotoxic chemotherapy within 48 hours prior or after the SRS or WBRT. • Primary germ cell tumour, small cell carcinoma, or lymphoma. • Widespread definitive leptomeningeal metastasis. This includes cranial nerve palsy, leptomeningeal carcinomatosis, ependymal involvement, cranial nerve involvement on imaging, suspicious linear meningeal enhancement, or cerebrospinal fluid (CSF) positive for tumour cells. • A brain metastasis that is located ≤ 5 mm of the optic chiasm or either optic nerve. • Surgical resection of a brain metastasis (stereotactic biopsies will be allowed). • More than 15 brain metastases on a volumetric T1 contrast MRI (voxels of 1mm or smaller) performed within the past 14 days, or more than 10 metastases in the case of a non-volumetric MRI. • Prior allergic reaction to memantine. • Current alcohol or drug abuse. • Current use of NMDA antagonists, such as amantadine, ketamine, or dextromethorphan. • Diagnosis of chronic liver disease/cirrhosis of the liver (e.g. Child-Pugh class B or C).