Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Essai de phase III comparant l'observation à la radiothérapie dans le cas d'un méningiome de grade II ayant fait l'objet d'une ablation chirurgicale complète.
Protocole ID	NRG-BN003
ClinicalTrials.gov ID	NCT03180268
Type(s) de cancer	Cerveau (SNC)
Phase	Phase III
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Jean-Paul Bahary
Coordonnateur	Diane Trudel 514-890-8000 poste 11181
Statut	Fermé
Date d'activation	28-06-2018
But étude	This randomized phase III trial studies how well radiation therapy works compared with observation in treating patients with newly diagnosed grade II meningioma that has been completely removed by surgery. Radiation therapy uses high energy x-rays to kill tumor cells and shrink tumors.
Critères d'éligibilité	• PRIOR TO STEP 1 REGISTRATION: • The patient must have a newly diagnosed unifocal intracranial meningioma, gross totally resected, and histologically confirmed as WHO grade II based upon pathology findings at the enrolling institution; WHO grade will be assigned according to WHO 2016 criteria • Gross total resection (GTR) will be interpreted as modified Simpson grade 1-3 without gross residual dural-based or extradural tumor; GTR must be confirmed both by modified Simpson grade and by post-operative magnetic resonance imaging (MRI) findings • Step 1 registration must occur within 180 days of the initial surgery; within this 180 day interval, a second surgery is permitted in order to achieve GTR, but even with a second surgery, step 1 registration must occur within 180 days of the initial resection • For step 1 registration the operating neurosurgeon must provide the modified Simpson grade • GTR must be confirmed on post-operative imaging following the most recent surgery; submission of both pre-operative and post-operative MRIs is required for patients; if a second surgery is performed, submission of post-operative MRI is required and pre-operative MRI is required only if obtained; all sequences obtained in the pre- and post-operative MR imaging are to be submitted to National Radiology Group (NRG) Oncology for study registration; imaging subsequent to enrollment must include pre and post gadolinium contrast-enhanced three-dimensional spoiled gradient (SPGR), magnetization-prepared rapid gradient echo (MP-RAGE), or turbo field echo (TFE) MRI scan and an axial T2 fluid attenuated inversion recovery (FLAIR) sequence; to yield acceptable image quality, the gadolinium contrast-enhanced three-dimensional SPGR, MP-RAGE, or TFE axial MRI scan should use the smallest possible axial slice thickness not exceeding 1.5 mm; the post-operative MRI must be completed within sufficient time to permit step 1 registration within 180 days of the initial resection; these same conditions apply in the setting of a second surgical procedure, although if a second surgery is completed, step 1 registration must still occur with 180 days of initial surgery; computed tomography (CT) imaging is not required, but may be obtained if desired clinically, for instance to assess calcifications or hyperostosis • The patient or a legally authorized representative must provide study-specific informed consent prior to study entry • If the patient is a primary English speaker, the patient must participate in the NCF and patient reported outcomes part of the study; if the patient is a primary French or Spanish speaker, the patient must participate in the patient reported outcomes part of the study • NOTE: Central pathology review must occur between steps 1 and 2 of registration; once

	appropriate pathology specimens are received, central pathology review will occur within 15 days, and must confirm WHO grade II meningioma before the patient can proceed to step 2 registration and randomization • PRIOR TO STEP 2 REGISTRATION: • Histologically confirmed diagnosis of WHO grade II meningioma confirmed by central pathology review prior to step 2 registration • History/physical examination, including neurologic examination within 60 days prior to step 2 registration • Post-operative Zubrod performance status 0-1 within 60 days prior to step 2 registration • If the patient is a woman is of childbearing potential, a serum pregnancy test, obtained within 14 days prior to step 2 registration, must be negative, and, if randomized to receive radiation therapy, the woman must agree to use contraception
Critères d'exclusion	• Optic nerve sheath meningioma, spinal or other extracranial meningioma, multiple meningiomas, hemangiopericytoma • Definitive evidence of metastatic meningioma • Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 3 years (carcinoma in situ of the breast, oral cavity, cervix, melanoma in situ, or other non-invasive malignancies are permissible) • Previous radiotherapy to the scalp, cranium, brain, or skull base and radiation-induced meningiomas • Major medical illnesses or psychiatric impairments, which in the investigators opinion, will prevent administration or completion of the protocol therapy and/or preclude informed consent; these include, but are not restricted to: • Unstable angina and/or congestive heart failure requiring hospitalization at the time of step 2 registration • Transmural myocardial infarction within the last 6 months prior to step 2 registration • Acute bacterial or fungal infection requiring intravenous antibiotics at the time of step 2 registration • Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of step 2 registration • Type II neurofibromatosis (NF2) • Ailments entailing substantial increases in sensitivity and side effect risk from radiation therapy (ataxia telangiectasia, Nijmegen breakage syndrome, and human immunodeficiency virus (HIV) with CD4 count < 200 cells/microliter); HIV testing is not required for eligibility for this protocol, and known HIV positive patients are eligible, provided they are under treatment with highly active antiretroviral therapy (HAART) and have a CD4 count >= 200 cells/microliter within 30 days prior to step 2 registration • Inability to undergo MRI with and without contrast (e.g. claustrophobia, non-MRI compatible implant or foreign body, etc) or receive gadolinium; note that patients with severe claustrophobia are permitted on this study if they are willing and able to undergo MRI with adequate sedation or anesthesia • Pregnancy and/or nursing females