Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer
Protocole ID	BRC.8 / SWOG S1827 (MAVERICK)
ClinicalTrials.gov ID	NCT04155034
Type(s) de cancer	Poumon à petites cellules
Phase	Phase III
Type étude	Clinique
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
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Statut	Actif en recrutement
But étude	This phase III trial studies magnetic resonance imaging (MRI) surveillance and prophylactic cranial irradiation (PCI) to see how well they work compared to MRI surveillance alone in treating patients with small cell lung cancer. MRI scans are used to monitor the possible spread of the cancer with an MRI machine over time. PCI is radiation therapy that is delivered to the brain in hopes of preventing spread of cancer into the brain. The use of brain MRI alone may reduce side effects of receiving PCI and prolong patients' lifespan. Monitoring with MRI scans alone (delaying radiation until the actual spread of the cancer) may be at least as good as the combination of PCI with MRI scans.
Critères d'éligibilité	• Patient must have a histologically confirmed diagnosis of small-cell lung cancer (SCLC) • Patient must have an MRI of the brain performed within 28 days prior to registration documenting no evidence of brain metastases or leptomeningeal disease. Patient also must not have a history of brain metastases or leptomeningeal disease • Immunotherapy concurrent with and/or adjuvant to first-line therapy is allowed at the discretion of the treating physician. Patients with limited-stage (LS)-SCLC must have completed platinum-based chemotherapy and either definitive thoracic radiotherapy (including stereotactic body radiation therapy [SBRT] for early-stage T1-2 N0 M0 disease who do not undergo surgery) or definitive surgical resection; thoracic radiation in addition to definitive surgical resection is allowed at the discretion of the treating physician, but is not required. Patients with extensive-stage (ES)-SCLC must have completed platinum-based chemotherapy either with or without thoracic radiotherapy at the discretion of the treating physician • All adverse events from prior treatment must have resolved to =< grade 2 (Common Terminology Criteria for Adverse Events [CTCAE] version 5.0) prior to randomization • Patient must have had a response to first-line therapy and no evidence of progression in opinion of the treating investigator. Systemic imaging (computed tomography [CT] or positron emission tomography [PET]/CT including the chest and abdomen) must be performed within 28 days prior to randomization • No more than 8 weeks may have elapsed between day 1 of the last cycle of chemotherapy and randomization • Patient must not have received prior radiotherapy to the brain or whole brain radiotherapy. Patients who have undergone prior stereotactic radiosurgery for benign tumors or conditions (e.g., acoustic neuroma, grade I meningioma, trigeminal neuralgia) may be considered on a case-by-case basis • Patient must have Zubrod performance status of 0-2 • Patient must not have a contraindication to MR imaging, such as implanted metal devices or foreign bodies

- Patient must not have a contraindication to gadolinium contrast administration during MR imaging, such as allergy or insufficient renal function
- Patient must not have other metastatic malignancies requiring current active treatment
- Patient must not have any severe active comorbidities, defined as follows:
    - Unstable angina and/or congestive heart failure requiring hospitalization within 6 months prior to randomization
    - Transmural myocardial infarction within 6 months prior to randomization
    - Acute bacterial or fungal infection requiring intravenous antibiotics at the time of randomization
    - Chronic obstructive pulmonary disease exacerbation or other acute respiratory illness precluding study therapy at the time of randomization
    - Severe hepatic disease defined as a diagnosis of Child-Pugh class B or C hepatic disease
    - Human immunodeficiency virus (HIV) positive with CD4 count < 200 cells/microliter
        - Note that patients who are HIV positive are eligible, provided they are under treatment with highly active antiretroviral therapy (HAART) and have a CD4 count >= 200 cells/microliter within 16 weeks prior to randomization
        - Note also that HIV testing is not required for eligibility for this protocol
- Patient must not be pregnant because of fetal risks from radiation exposure. Men must have agreed to use an effective contraceptive method during PCI and for six months after completing PCI. Women of reproductive potential must have agreed to use an effective contraceptive method during PCI. A woman is considered to be of "reproductive potential" if she has had menses at any time in the preceding 12 consecutive months. In addition to routine contraceptive methods, "effective contraception" also includes heterosexual celibacy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) defined as a hysterectomy, bilateral oophorectomy or bilateral tubal ligation. However, if at any point a previously celibate patient chooses to become heterosexually active during the time period for use of contraceptive measures outlined in the protocol, he/she is responsible for beginning contraceptive measures
- Patients who speak and understand English or French must agree to participate in cognitive function testing
- Patient must be offered the opportunity to have specimens submitted for banking
- Patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines
- As a part of the Oncology Patient Enrollment Network (OPEN) randomization process the treating institution?s identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system

Critères d'exclusion	