# Essai Clinique

Généré le 18 avr. 2024 à partir de

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| Titre | Essai clinique de phase IIR/III de soins standards avec ou sans Radiothérapie Stéréotactique Extra-crânienne (SBRT) et/ou ablation chirurgicale du cancer du sein nouvellement Oligométastatique |
| Protocole ID | NRG-BR002 |
| ClinicalTrials.gov ID | NCT02364557 |
| Type(s) de cancer | Sein |
| Phase | Phase III |
| Institution | CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL |
| Ville | Montréal |
| Investigateur principal | Dre Laura Masucci |
| Coordonnateur | Diane Trudel<br>514-890-8000 poste 11181 |
| Statut | Fermé |
| Date d'activation | 04-02-2016 |
| But étude | This randomized phase II/III trial studies how well standard of care therapy with stereotactic radiosurgery and/or surgery works and compares it to standard of care therapy alone in treating patients with breast cancer that has spread to one or two locations in the body (limited metastatic) that are previously untreated. Standard of care therapy comprising chemotherapy, hormonal therapy, biological therapy, and others may help stop the spread of tumor cells. Radiation therapy and/or surgery is usually only given with standard of care therapy to relieve pain; however, in patients with limited metastatic breast cancer, stereotactic radiosurgery, also known as stereotactic body radiation therapy, may be able to send x-rays directly to the tumor and cause less damage to normal tissue and surgery may be able to effectively remove the metastatic tumor cells. It is not yet known whether standard of care therapy is more effective with stereotactic radiosurgery and/or surgery in treating limited metastatic breast cancer. |
| Critères d'éligibilité | • Pathologically confirmed metastatic breast cancer within 270 days prior to registration<br>• Known estrogen, progesterone, and HER2 status of either primary tumor or metastasis<br>• =< 2 metastases seen on standard imaging within 30 days prior to registration<br>• Controlled primary tumor site defined as >= 3 months (90 days) recurrence-free interval since completion of definitive surgical management<br>• All known disease amenable to metastasis-directed therapy with either SBRT or resection<br>• NOTE: Symptomatic bone metastasis are allowed if ablative therapy can be delivered<br>• NOTE: Sites for possible surgical excision include lung, liver, adrenal gland, bone, small intestine, large intestine, ovary, and amenable nodal disease sites<br>• NOTE: Surgical stabilization is allowed for a metastasis if it is followed by conventionally fractionated external beam radiotherapy<br>• Maximum diameter of individual metastasis in any dimension =< 5 cm<br>• Metastases must be > 5 cm away from each other (defined as Edge to Edge of tumor)<br>• NOTE: If metastases are =< 5 cm away from each other, consider enrollment in NRG-BR001<br>• First-line standard systemic therapy (chemotherapy, anti-endocrine therapy, anti-HER2 or other standard targeted therapy) for metastatic breast cancer not to have exceeded a duration of 6 months at the time of registration<br>• Appropriate stage for study entry based on the following diagnostic workup:<br>• History/physical examination within 30 days prior to registration<br>• Computed tomography (CT) scans of the chest, abdomen, and pelvis with radionuclide bone scan OR whole body positron emission tomography (PET)/CT within 30 days prior to study registration<br>• Zubrod performance status =< 2 within 30 days prior to registration<br>• Absolute neutrophil count (ANC) >= 500 cells/mm^3<br>• Platelets >= 50,000 cells/mm^3 |

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| | • Hemoglobin >= 8.0 g/dl (note: the use of transfusion or other intervention to achieve hemoglobin [Hgb] >= 8.0 g/dl is acceptable)<br>• For females of child-bearing potential, negative serum or urine pregnancy test within 14 days prior to study registration<br>• The patient must provide study-specific informed consent prior to study entry |
| Critères d'exclusion | • Pathologic evidence of local/regional breast tumor recurrence<br>• Co-existing or prior invasive malignancy (except non-melanomatous skin cancer), unless disease free for a minimum of 3 years<br>• Metastases with indistinct borders making targeting not feasible<br>• NOTE: A potential issue with bone metastases is that they often are not discrete; since many patients on this protocol will have bone metastases, this will be an important issue; theoretically, Houndsfield units might provide an appropriate measure; however, a sclerotic lesion against dense cortical bone will not have a sharp demarcation based on Houndsfield units (HU); therefore, we acknowledge that such determinations will pose a challenge and thus the physician's judgment will be required<br>• Prior palliative radiation treatment for metastatic disease<br>• Metastases located within 3 cm of the previously irradiated structures:<br>• Spinal cord previously irradiated to > 40 Gy<br>• Brachial plexus previously irradiated to > 50 Gy<br>• Small intestine, large intestine, or stomach previously irradiated to > 45 Gy<br>• Brainstem previously irradiated to > 50 Gy<br>• Lung previously irradiated with prior V20Gy > 30%<br>• Brain metastases<br>• Exudative, bloody, or cytological proven malignant effusions<br>• Severe, active co-morbidity defined as follows:<br>• Unstable angina and/or congestive heart failure requiring hospitalization within the last 6 months<br>• Transmural myocardial infarction within the last 6 months<br>• Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration<br>• Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of registration<br>• Pregnancy; lactating females must cease expression of milk prior to signing consent to be eligible<br>• Human immunodeficiency virus (HIV) positive with cluster of differentiation (CD)4 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 30 days prior to registration; note also that HIV testing is not required for eligibility for this protocol |