Essai Clinique

Généré le 22 mai 2025 à partir de

Titre	Concordance entre la biopsie liquide et la biopsie tissulaire dans les cas de cancer du sein métastatique nouvellement diagnostiqué
Protocole ID	Concordance
ClinicalTrials.gov ID	NCT04241237
Type(s) de cancer	Sein
Phase	Autres
Type étude	Autre
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
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Statut	Actif en recrutement
But étude	Tissue biopsy is a procedure to remove a piece of tissue (sample of cells) from the body to be analyzed in a laboratory, and it is commonly performed to confirm diagnosis of a patient with symptoms of breast cancer recurrence. It may also provide information on tumor markers (hormone receptors, HER2) that can guide treatment decisions. The goal of this study is to determine whether blood tests (which require less-invasive procedures) can be used to confirm diagnosis of suspected recurrent breast cancer (as compared to tissue biopsy).Investigators plan to investigate blood factors which include circulating tumor cells (CTCs - i.e., cancer cells that can be detected in the blood), circulating tumor DNA (ctDNA - i.e., pieces of DNA from cancer cells that can be found in the blood), as well as other biomarkers. Investigators will conduct this study in 120 participants who present with suspected breast cancer recurrence and symptoms of cancer that has spread to other areas in the body. Participants will be asked for blood collection within 30 days before tissue biopsy. The tissue will be analysed locally to determine the presence of cancer and the tumor markers listed above. The blood will be processed and stored for analysis of CTCs and ctDNA. If these blood tests show concordance with tissue based tests (presence of cancer cells, hormone receptors & HER2 status), these tests could be used in future studies to confirm diagnosis using a non-invasive procedure. Also, investigators believe that the results of this study can influence other research of early-stage recurrent breast cancer.
Critères d'éligibilité	• Adult (≥18 years of age) diagnosed with primary breast cancer (BC) any subtype ER/PgR+ and HER2, triple negative or HER2+ at least 6 months before suspected metastases were identified • Patients must have suspected recurrent metastatic BC that will be confirmed by tissue biopsy that is expected to yield tissue adequate for histologic examination (sampling expected to yield material for cytologic evaluation only does not satisfy this criterion) • The suspected metastases must be outside the ipsilateral breast, axilla infra/supraclavicular areas. In those with suspected metastases in contralateral axilla, infra/supraclavicular areas only a new contralateral breast primary must be excluded by physical exam, mammogram and MRI
Critères d'exclusion	• Only locoregional recurrence (ipsilateral breast, axilla, infra/supraclavicular) suspected (see above regarding potential contralateral axillary or infra/supraclavicular metastases as only site of metastasis) • Tissue biopsy occurs prior to blood collection for CTCs and ctDNA • New treatment for suspected metastases commences prior to blood collection for CTCs and ctDNA • Patient has received previous lines of systemic treatment for metastatic BC

- Previous history of an invasive non-BC apart from cancers treated with curative intent at least 5 years previously with no recurrence since diagnosis, with the exception of a non-melanoma skin cancer
- Patients unable or unwilling to undergo a tissue biopsy
- Patients unable to provide informed consent
- Patients undergoing only cytologic evaluation of suspected metastases