Essai Clinique

Généré le 21 mai 2025 à partir de

Titre	A Randomized, Double-blind, Phase 3 Study of Tucatinib or Placebo in Combination With Trastuzumab and Pertuzumab as Maintenance Therapy for Metastatic HER2+ Breast Cancer
Protocole ID	HER2CLIMB-05
ClinicalTrials.gov ID	NCT05132582
Type(s) de cancer	Sein
Phase	Phase III
Stade	Métastatique
Type étude	Clinique
Médicament	Tucatinib ou placebo avec trastuzumab et pertuzumab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Jean-Pierre Ayoub
Coordonnateur	Ana Lydia Tkalec 514-890-8000 poste 14186
Statut	Actif en recrutement
Date d'activation	06-03-2023
But étude	This study is being done to see if tucatinib works better than placebo when given with other drugs to treat participants with HER2-positive breast cancer. A placebo is a pill that looks the same as tucatinib but has no medicine in it. This study will also test what side effects happen when participants take this combination of drugs. A side effect is anything a drug does to the body besides treating your disease. Participants will have cancer that has spread in the body near where it started (locally advanced) and cannot be removed (unresectable) or has spread through the body (metastatic). In this study, all participants will get either tucatinib or placebo. Participants will be assigned randomly to a group. This is a blinded study, so patients and their doctors will not know which group a participant is in. All participants will also get trastuzumab and pertuzumab. These are 2 drugs used to treat this type of cancer.

Critères d'éligibilité	• Centrally confirmed HER2+ breast carcinoma per 2018 American Society of Clinical Oncologists (ASCO) College of American Pathologists (CAP) guidelines.
	• Have unresectable locally advanced or metastatic disease.
	  • If recurrent (after [neo]adjuvant therapy), must be at least 6 month treatment free from any trastuzumab or pertuzumab received for advanced HER2+ disease.
	• Have received 4-8 cycles (21 day cycles) of previous treatment with trastuzumab, pertuzumab, and taxane as first-line therapy for advanced HER2+ breast cancer with no evidence of disease progression
	• Known hormone receptor status (per local guidelines; may be hormone receptor positive [HR+] or negative [HR-])
	• Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
	• CNS Inclusion - Based on screening contrast brain magnetic resonance imaging (MRI), participants may have any of the following:
	  • No evidence of brain metastases
	  • Untreated brain metastases which are asymptomatic and, if identified on prior brain imaging, without evidence of progression since starting first-line induction therapy with trastuzumab, pertuzumab, and taxane
	  • Previously treated brain metastases which are asymptomatic

	• Brain metastases previously treated with local therapy must not have progressed since treatment

Critères d'exclusion	• Prior treatment with any anti-HER2 and/or anti-epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor including pyrotinib, lapatinib, tucatinib, neratinib, and afatinib (except neratinib if given in extended adjuvant setting and ≥ 12 months have elapsed since last neratinib dose prior to start of study drug)
	• Unable to undergo contrast MRI of the brain
	• CNS Exclusion - Based on screening brain MRI and clinical assessment
	  • Symptomatic brain metastasis
	  • Progression of brain metastases since starting first line trastuzumab, pertuzumab, and taxane
	  • Ongoing use of systemic corticosteroids at a total daily dose of >2 mg of dexamethasone (or equivalent)
	  • Any untreated brain lesion in an anatomic site which may pose risk to participant
	  • Known or suspected leptomeningeal disease (LMD)
	  • Poorly controlled (>1/week) seizures, or other persistent neurologic symptoms