Essai Clinique

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Titre	Randomized, OpEn-Label, Active-ContrOl Trial of SPI-2012 (Eflapegrastim) Versus Pegfilgrastim in the Management of Chemotherapy-Induced Neutropenia in Early-Stage BReast Cancer Patients Receiving Docetaxel and Cyclophosphamide (TC) (RECOVER)
Protocole ID	RECOVER ADVANCE2 (SPI-GCF-302)
ClinicalTrials.gov ID	NCT02953340
Type(s) de cancer	Sein
Phase	Phase III
Stade	Adjuvant
Type étude	Support
Médicament	Eflapegrastim vs Pegfilgrastim
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
Investigateur principal	Dre Brigitte Poirier
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Statut	Fermé
But étude	The purpose of this study is to compare the efficacy of SPI-2012 with pegfilgrastim in patients with early-stage breast cancer receiving docetaxel and cyclophosphamide (TC) to prevent and reduce Neutropenia that is associated with cancer chemotherapy.
Critères d'éligibilité	• New diagnosis of histologically confirmed early-stage breast cancer (ESBC), defined as operable Stage I to Stage IIIA breast cancer. • Candidate to receive adjuvant or neo-adjuvant TC chemotherapy. • ECOG ≤2. • ANC ≥1.5×10^9/L. • Platelet count ≥100×10^9/L. • Hemoglobin >9 g/dL. • Calculated creatinine clearance > 50 mL/min. • Total bilirubin ≤1.5 mg/dL. • AST/SGOT and ALT/SGPT ≤2.5×ULN. (upper limit of normal) • Alkaline phosphatase ≤2.0×ULN.
Critères d'exclusion	• Active concurrent malignancy (except non melanoma skin cancer or carcinoma in situ of the cervix) or life-threatening disease. • Known sensitivity to E. coli derived products. • Concurrent adjuvant cancer therapy. • Locally recurrent/metastatic. • Previous exposure to filgrastim, pegfilgrastim, or other G-CSF products in clinical development within 12 months prior to the administration of study drug. • Active infection or any serious underlying medical condition, which would impair the ability of the patient to receive protocol treatment. • Prior bone marrow or stem cell transplant.

- Used any investigational drugs, biologics, or devices within 30 days prior to study treatment or plans to use any of these during the course of the study.
- Prior radiation therapy within 30 days prior to enrollment.
- Major surgery within 30 days prior to enrollment.