Essai Clinique

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Titre	Essai randomisé du SPI-2012 versus le pegfilgrastim dans la gestion de la neutropénie induite par la chimiothérapie chez les patients atteints d'un cancer du sein et qui sont traités au docetaxel et au cyclophosphamide (TC) (ADVANCE)
Protocole ID	SPI-GCF-301
ClinicalTrials.gov ID	NCT02643420
Type(s) de cancer	Sein
Phase	Phase III
Médicament	SPI-2012 Versus Pegfilgrastim
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Statut	Fermé
But étude	The purpose of this study is to compare the efficacy of a single dose of SPI-2012 with pegfilgrastim (Neulasta [NDC 55513-190-01] manufactured by Amgen) in patients with early-stage breast cancer receiving docetaxel and cyclophosphamide (TC), as measured by the Duration of Severe Neutropenia (DSN) in Cycle 1.
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 • Alkaline phosphatase ≤1.5×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 or known sensitivity to any of the products to be administered during dosing • Concurrent adjuvant cancer therapy • Locally recurrent/metastatic or contralateral breast cancer. • Previous exposure to filgrastim, pegfilgrastim, or other G-CSF products in clinical development 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.