Essai Clinique

Généré le 25 avr. 2024 à partir de

Titre	Une étude de phase III randomisée, multicentrique et en groupes parallèles visant à comparer l'efficacité de l'arfolitixorine à celle de la leucovorine en association avec le 5 fluorouracile, l'oxaliplatine et le bévacizumab chez des patients atteints d'un cancer colorectal avancé
Protocole ID	ISO-CC-007
ClinicalTrials.gov ID	NCT03750786
Type(s) de cancer	Côlon et rectum
Phase	Phase III
Institution	CISSS DE LAVAL HOPITAL DE LA CITE-DE-LA-SANTE 1755 boul. René-Laennec, Laval, QC, H7M 3L9
Ville	Laval
Investigateur principal	Dr Nathalie Aucoin
Coordonnateur	Solange Tremblay 450-668-1010 poste 23603
Statut	Fermé
But étude	This is a multicenter, randomized, parallel-group, Phase III study in at least 440 patients with advanced colorectal cancer to compare the efficacy of treatment with arfolitixorin versus Leucovorin in combination with 5-fluorouracil, oxaliplatin, and bevacizumab according to modified FOLFOX-6 until PD according to RECIST 1.1 criteria.
Critères d'éligibilité	**For randomization in the study, patients must fulfill all of the following criteria:** • Colorectal adenocarcinoma verified by biopsy. • Availability of biopsy material, from the primary tumor or metastasis, allowing for analysis of tumor gene expression. • Non-resectable metastatic CRC planned for first line therapy with 5-FU, oxaliplatin, and bevacizumab. • Evaluable disease with at least one measurable lesion of metastatic disease (≥10 mm in longest diameter on axial image on CT-scan or alternatively MRI with <5 mm reconstruction interval) within 28 days of randomization. • Life expectancy of more than 4 months. • ECOG performance status 0 or 1. • Hemoglobin (Hb) > 100 g/L, Absolute neutrophil count (ANC) > 1.5x109/L. Thrombocytes > 100x109/L. • Creatinine clearance > 50 mL/min, Total bilirubin < 1.5 x ULN, AST and ALT < 3 x ULN (and < 5 x ULN in case of liver metastases). • Male or female ≥18 years of age. • Female patients of childbearing potential must have a negative urine pregnancy test and use adequate contraceptive measures • Male patients must use adequate contraceptive measures • Voluntarily signed informed consent before performance of any study related procedure not part of normal medical care, with the understanding that consent may be withdrawn by the patient at any time without prejudice to future medical care. • Female patients must be post-menopausal for more than one year or must provide a negative pregnancy test and use an efficient method of contraception (i.e., a method with less than 1% failure rate [e.g., sterilization, hormone implants, hormone injections, some intrauterine devices, or vasectomized partner]) during the study and for 1 month (or more if requested by non-IMP labels) after the end of the study (last dose of IMP). • Unless the partner of a male patient is post-menopausal or using an efficient method of

	contraception as described above, male patients must agree to use condoms during the study treatment and for 1 month after the end of the study treatment.
Critères d'exclusion	**Patients meeting one or more of the following criteria are ineligible to participate in the study:** • Malignant tumors other than colorectal adenocarcinomas (current or within the previous five years), with the exception for curatively treated non-melanoma skin cancer or in situ carcinoma of the cervix. • Less than 6 months between randomization and completion of the last anti-cancer treatment (chemotherapy/ radiotherapy/immunotherapy/surgery, etc.). (NB: Rectal cancer treatment shorter than 8 weeks of chemo/radiation therapy is allowed.) • Confirmation of progressive disease within 6 months after completion of prior anti-cancer treatment. • Indication for any mCRC surgery or anti-cancer treatment other than study treatment. • Prior treatment with arfolitixorin. • Indication for treatment with a 5-FU analogue, or 5-FU for a condition other than mCRC. • Known DPD deficiency. • Known or suspected central nervous system metastases. • Unresolved bowel obstruction, uncontrolled Crohn’s disease, or ulcerative colitis. • History of cardiac disease with a New York Heart Association Class II or greater, congestive heart failure, myocardial infarction or unstable angina at any time during the 6 months prior to randomization, or serious arrhythmias requiring medication for treatment. • Current CTCAE ≥ grade 3 diarrhea. • Current chronic infection or uncontrolled serious illness causing immunodeficiency. • Known or suspected hypersensitivity or intolerance to arfolitixorin, LV, 5-FU, oxaliplatin, or bevacizumab. • Breastfeeding patients. • Patient who received investigational drugs in other clinical trials within 28 days, or 5 half-lives of the investigational drug, prior to randomization. • Patient with serious medical or psychiatric illness likely to interfere with participation in this clinical study. • Ongoing drug or alcohol abuse, as deemed by the Investigator. • Any condition that, in the opinion of the Investigator, could compromise the patient's safety or adherence to the study protocol. • Involvement, or related to people involved in the planning or conduct of the study (applies to both Isofol Medical staff and staff at the study site).