Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude de phase III portant sur une radiothérapie palliative contre un carcinome hépatocellulaire symptômatique et des métastases au foie
Protocole ID	NCIC HE.1
ClinicalTrials.gov ID	NCT02511522
Type(s) de cancer	Foie
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
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But étude	The purpose of this study is to see whether one dose of palliative radiation therapy directed to the liver in combination with standard BSC might help to reduce liver pain/discomfort due to cancer when compared to getting standard BSC alone.
Critères d'éligibilité	• A diagnosis of cancer by at least one criterion listed below: • Pathologically or cytologically proven carcinoma from primary site or site of metastases; • Pathologically or cytologically proven HCC; • HCC diagnosed by standard imaging criteria: arterial enhancement and delayed washout on multiphasic computerized tomography (CT) or magnetic resonance imaging (MRI) in the setting of cirrhosis or chronic hepatitis B or C without cirrhosis. • Largest burden of cancer in the liver is confirmed with CT scan or MRI corresponding to the clinically painful area done within 120 days prior to randomization. • Diffuse (infiltrative involving > 50% of the liver), multifocal (> 10 lesions) or locally advanced cancer (at least one lesion > 10cm, vascular invasion, or multiple lesions with at least one > 6cm) involving the liver. • In the investigator's opinion, patient is unsuitable for or refractory to standard local and regional therapies. For example: • HCC unsuitable for resection, radiofrequency ablation (RFA), transarterial chemo embolization (TACE) or radical intent, ablative dose stereotactic body radiation therapy (SBRT); • Colorectal carcinoma metastases unsuitable for resection, RFA or radical intent, ablative dose SBRT (e.g. SBRT, > 30 Gy in 5 fractions, may be an option for up to 3 metastases < 5cm each, or up to 5 metastases < 3 cm each). • Unsuitable for, high risk for, or refractory to, standard systemic chemotherapy or targeted therapy (e.g. sorafenib). • Patient reports moderate or severe pain/discomfort prior to the baseline evaluation and this pain is considered "stable" over a period of up to 7 days prior to randomization. • Definition of moderate pain: • Patient reports level of 4-6 (on a BPI scale from 0 to 10) pain or discomfort "at its worst in the past 24 hours", occurring in the right upper quadrant of the abdomen, the upper abdomen and/or referred to the right shoulder, attributable to liver cancer.

	• Definition of severe pain: • Patient reports level of 7-10 (on a BPI scale from 0 to 10) pain or discomfort "at its worst in the past 24 hours", occurring in the right upper quadrant of the abdomen, the upper abdomen and/or referred to the right shoulder, attributable to liver cancer. • Definition of "stable" pain: • Patient must show moderate or severe "stable" pain by reporting a score of 4 or greater (on 2 separate days within the 7 day period prior to randomization) with the difference of these scores being 0, 1, 2 or 3. • Patient reports moderate or severe pain (i.e. pain score is 4 or higher). This baseline score must also be stable compared to the most recent pre-baseline pain score with the difference between these scores being 0, 1, 2, or 3. • Blood work obtained within 14 days prior to randomization as follows: • Hemoglobin > 70 g/L; • Platelets > 25 x 10^9/L • Absolute neutrophil count (ANC) > 1.0 x 10^9/L • INR < 3; • Bilirubin < 2.5 UNL (except for subjects with Gilbert's Disease who are eligible despite elevated serum bilirubin level) • AST or ALT < 10 x ULN. • Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0-3 within 14 days of Randomization (see Appendix II). • Life expectancy of > 3 months. • 18 years of age or older at the time of randomization. • Patient is willing to complete the Pre-Baseline Pain/Discomfort Questionnaire and the Pain/Discomfort and Medication Questionnaire in English, French or other validated language (please contact the HE.1 Study Coordinator). The baseline assessment must be completed within required timelines prior to randomization. Unwillingness to complete the Pre-Baseline Pain/Discomfort Questionnaire and Pain/Discomfort and Medication Questionnaire will make the patient ineligible for the study. • Patient is able (i.e. sufficiently fluent) and willing to complete the QoL questionnaires in English, French or other languages in which the FACT-Hep is available. The baseline assessment must be completed within required timelines prior to randomization. • Inability (illiteracy in languages listed above, loss of sight, or other equivalent reason) to complete the questionnaires will not make the patient ineligible for the study. However, ability but unwillingness to complete the QoL questionnaires will make the patient ineligible for QoL assessment. • Patient is not pregnant, planning on becoming pregnant or planning on fathering a child in the next 90 days. • Women/men of childbearing potential must have agreed to use a highly effective contraceptive method. A woman is considered to be of "childbearing potential" if she has had menses at any time in the preceding 12 consecutive months. In addition to routine contraceptive methods, "effective contraception" also includes heterosexual celibacy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) defined as a hysterectomy, bilateral oophorectomy or bilateral tubal ligation, or vasectomy/vasectomized partner. However, if at any point a previously celibate patient chooses to become heterosexually active during the time period for use of contraceptive measures outlined in the protocol, he/she is responsible for beginning contraceptive measures. • Women of childbearing potential will have a pregnancy test to determine eligibility as part of the Pre-Study Evaluation; this may include an ultrasound to rule-out pregnancy if a false-positive is suspected. For example, when beta-human chorionic gonadotropin is high and partner is vasectomized, it may be associated with tumour production of hCG, as seen with some cancers. Patient will be considered eligible if an ultrasound is negative for pregnancy • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrolment in the trial to document their willingness to participate; • Patients must be accessible for treatment and follow-up. Investigators must ensure the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up. • In accordance with NCIC CTG policy, protocol treatment is to begin within 5 working days of patient randomization (earlier is preferred).
Critères d'exclusion	• Prior radiotherapy to the upper abdomen that would result in substantial overlap of the irradiated volume (e.g. > 50% of liver receiving > 24 Gy in 2 Gy equivalent dose); • Prior selective internal radiotherapy directed to the liver or hepatic arterial yttrium therapy, at any time. • Cholangitis or acute bacterial infection requiring intravenous antibiotics within 28 days prior to study entry. • Radiographic evidence of intrabiliary cancer within the common or main branches of the biliary system, < 4 months prior to randomization. • Child-Pugh score greater than C10 (a score of C10 is allowed). • Chemotherapy or TACE administered within the past 4 weeks. • Targeted therapy (e.g. Sorafenib) received within the past 2 weeks. • Plans for chemotherapy, targeted therapy or TACE in the next 4 weeks.