Essai Clinique

Généré le 28 avr. 2025 à partir de

Titre	Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk With Radiation
Protocole ID	PREDICT-RT*
ClinicalTrials.gov ID	NCT04513717
Type(s) de cancer	Prostate
Phase	Phase III
Type étude	Clinique
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
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Statut	Actif en recrutement
Date d'activation	29-01-2024
But étude	This phase III trial compares less intense hormone therapy and radiation therapy to usual hormone therapy and radiation therapy in treating patients with high risk prostate cancer and low gene risk score. This trial also compares more intense hormone therapy and radiation therapy to usual hormone therapy and radiation therapy in patients with high risk prostate cancer and high gene risk score. Apalutamide may help fight prostate cancer by blocking the use of androgen by the tumor cells. Radiation therapy uses high energy rays to kill tumor cells and shrink tumors. Giving a shorter hormone therapy treatment may work the same at controlling prostate cancer compared to the usual 24 month hormone therapy treatment in patients with low gene risk score. Adding apalutamide to the usual treatment may increase the length of time without prostate cancer spreading as compared to the usual treatment in patients with high gene risk score.

Critères d'éligibilité	**PRIOR TO STEP 1 REGISTRATION**
	• Pathologically proven diagnosis of adenocarcinoma of prostate cancer within 180 days prior to registration
	• High-risk disease defined as having at least one or more of the following:
	  • PSA > 20 ng/mL prior to starting ADT Note: Patients receiving a 5-alpha reductase inhibitor (ex. finasteride) at the time of enrollment are eligible. The baseline PSA value should be doubled for PSAs taken while on 5-alpha reductase inhibitors and the medication should be discontinued prior to randomization but a washout period is not required.
	  • cT3a-T4 by digital exam or imaging (American Joint Committee on Cancer [AJCC] 8th edition [Ed.])
	  • Gleason score of 8-10
	  • Node positive by conventional imaging with a short axis of at least 1.0 cm
	• Appropriate stage for study entry based on the following diagnostic workup:
	  • History/physical examination within 120 days prior to registration;
	  • Bone imaging within 120 days prior to registration;
	  • Note: To be eligible, patient must have no definitive evidence of bone metastases (M0) on bone scan or sodium fluoride (NaF) PET within 120 days prior to registration (negative NaF PET/CT or negative Axumin or choline PET or negative fluciclovine, choline or prostate-specific membrane antigen (PSMA)

PET within 120 days prior to registration is an acceptable substitute if they have been performed). Patients who have bone metastases established only fluciclovine, choline, or PSMA PET but not definitive on bone scan or NaF PET will still be eligible
    - CT or MRI of the pelvis within 120 days prior to registration (negative fluciclovine, choline, or PSMA PET within 120 days prior to registration is an acceptable substitute). As with bone staging, nodal staging for trial purposes will be based off of conventional imaging findings only
    - Patients with confirmed N1 metastases on conventional imaging (CT/MRI) as defined by ≥10 mm on short axis are eligible but will be automatically assigned to the intensification study. Patients who are positive by fluciclovine, choline, or PSMA PET (i.e. N1), but whose nodes do not meet traditional size criteria for positivity (i.e. they measure ≥ 10 mm on either the CT or MRI portion of the PET or on a dedicated CT or MRI) will not be considered N1 for the trial and will not automatically be assigned to the intensification study
- Age ≥ 18
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 within 120 days prior to registration
- Hemoglobin ≥ 9.0 g/dL, independent of transfusion and/or growth factors (within 120 days prior to registration)
- Platelet count ≥ -100 x 10^3/uL independent of transfusion and/or growth factors (within 120 days prior to registration)
- Creatinine clearance (CrCl) ≥ 30 mL/min estimated by Cockcroft-Gault equation (within 120 days prior to registration)
    - For Black patients whose renal function is not considered adequate by Cockcroft-Gault formula, an alternative formula that takes race into account (Chronic Kidney Disease Epidemiology Collaboration CKD-EPI formula) may be used for calculating creatinine clearance for trial eligibility
    - Either a CrCl ≥ 30 ml/min or calculated glomerular filtration rate (GFR) ≥ 30 will make a patient eligible
- Total bilirubin =< 1.5 x institutional upper limit of normal (ULN) (within 120 days prior to registration)
    - Note: In subjects with Gilbert's syndrome, if total bilirubin is > 1.5 x ULN, measure direct and indirect bilirubin and if direct bilirubin is ≤ 1.5 x ULN, subject is eligible
- Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase [SGOT]) or alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase [SGPT]) ≤ 2.5 x institutional ULN (within 120 days prior to registration)
- Serum albumin ≥ 3.0 g/dL (within 120 days prior to registration)
- The patient must agree to use a condom (even men with vasectomies) and another effective method of birth control if he is having sex with a woman of childbearing potential or agree to use a condom if he is having sex with a woman who is pregnant while on study drug and for 3 months following the last dose of study drug
- Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial and have a CD4 count ≥ 200 cells/microliter within 60 days prior to registration. Note: HIV testing is not required for eligibility for this protocol. Of note, for patients with HIV in the intensification trial randomized to apalutamide, highly active antiretroviral therapy (HAART) may need to be adjusted to medications that do not interact with apalutamide
- For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable after or on suppressive therapy within 60 days prior to registration, if indicated. Note: HBV viral testing is not required for eligibility for this protocol
- Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial. Note: Any patient with a cancer (other than keratinocyte carcinoma or carcinoma in situ or low-grade non-muscle invasive bladder cancer) who has been disease-free for less than 3 years must contact the principal investigator
- The patient or a legally authorized representative must provide study-specific informed consent prior to study entry

PRIOR TO STEP 2 RANDOMIZATION

- Confirmation of Decipher score
- Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load within 60 days prior. Note: Apalutamide may interfere with HCV drugs. Patients on HCV medications should alert their infectious diseases physician if they get randomized to apalutamide due to the possibility that apalutamide can affect the bioavailability of some HCV medications. HCV viral testing is not required for eligibility for this protocol
- For patients entering the Intensification Cohort ONLY: Patients must discontinue or substitute concomitant medications known to lower the seizure threshold at least 30 days prior to Step 2 randomization

Critères d'exclusion	**PRIOR TO STEP 1 REGISTRATION:**
	• Definitive radiologic evidence of metastatic disease outside of the pelvic nodes (M1a, M1b or M1c) on conventional imaging (i.e. bone scan, CT scan, MRI)
	• Prior systemic chemotherapy within ≤ 3 years prior to registration; note that prior chemotherapy for a different cancer is allowed (completed > 3 years prior to registration
	• Prior radical prostatectomy
	• Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields
	• Current use of 5-alpha reductase inhibitor. NOTE: If the alpha reductase inhibitor is stopped prior to randomization the patient is eligible
	• History of any of the following:
	  • Seizure disorder
	  • Current severe or unstable angina
	  • New York Heart Association Functional Classification III/IV (Note: Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification.)
	  • History of any condition that in the opinion of the investigator, would preclude participation in this study
	• Evidence of any of the following at registration:
	  • Active uncontrolled infection requiring IV antibiotics
	  • Baseline severe hepatic impairment (Child Pugh Class C)
	  • Inability to swallow oral pills
	  • Any current condition that in the opinion of the investigator, would preclude participation in this study
	• Prior pharmacologic androgen ablation for prostate cancer is allowed only if the onset of androgen ablation (both luteinizing hormone-releasing hormone [LHRH] agonist and oral anti-androgen) is ≤ 60 days prior to registration; Please note: baseline PSA must be obtained prior to the start of any ADT
	PRIOR TO STEP 2 RANDOMIZATION:
	• Evidence of known gastrointestinal disorder affecting absorption of oral medications at registration
	• For patients entering the Intensification Cohort ONLY: Presence of uncontrolled hypertension (persistent systolic blood pressure [BP] ≥ 160 mmHg or diastolic BP ≥ 100 mmHg). Subjects with a history of hypertension are allowed, provided that BP is controlled to within these limits by anti-hypertensive treatment