Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	Étude randomisée, à double insu, avec un contrôle placebo évaluant le rôle de la metformine dans la réduction de la progression du cancer de la prostate à bas risque traité par approche conservatrice
Protocole ID	MAST (Metformin Active Surveillance Trial)
ClinicalTrials.gov ID	NCT01864096
Type(s) de cancer	Prostate
Phase	Phase III
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Fred Saad
Coordonnateur	Any Tétreault 514-890-8000 poste 26608
Statut	Fermé
But étude	This study aims to see if metformin can delay the time to progression in men with low risk prostate cancer when compared to a placebo.
Critères d'éligibilité	• Must be male > 18 and < 80 years of age • Have biopsy proven, low-risk, localized prostate cancer choosing expectant management as primary treatment ≤ 1year. [For the purposes of assessing subject eligibility a diagnostic biopsy must have included at least 10 cores, < 3 cores positive and < 50% of any one core positive) and must have been obtained within 6 months of screening]. Initial diagnosis of T1a/T1b obtained during a TURP is not allowed • Gleason score ≤ 6 [Gleason pattern 4 or above must not be present on any biopsy (initial or entry)] • Clinical stage T1c-T2a • Serum PSA ≤10 ng/mL (prior to biopsy) • Life expectancy greater than 5 years, as judged by the treating clinician/urologist • Able to swallow and retain oral medication • Hemoglobin A1c < 6.5% • Able and willing to participate in the full 3 years of the study • Able to understand instructions related to study procedures • Able to read and write (health outcome questionnaires are self-administered), understand instructions related to study procedures and give written informed consent
Critères d'exclusion	• Subject that has ever been treated for prostate cancer • Current and/or previous use of the following medications: 1-Use of 5α-reductase inhibitors (eg. Finasteride, Dutasteride) within the past 6 months of creening 2-Drugs with antiandrogenic properties (e.g., flutamide, bicalutamide, ketoconazole, progestational agents) within 6 months prior to screening • Previous or current diagnosis of type 1 or type 2 diabetes • Exposure to metformin within 12 months of screening • Planned or concurrent use of metformin hydrochloride, sulfonylureas, thiazolidinediones, or insulin for any reason • Known hypersensitivity or intolerance to metformin hydrochloride • Any condition associated with increased risk of metformin hydrochloride-associated lactic acidosis (e.g. congestive heart failure defines as NYHA class III or IV, history of any type of acidosis, habitual intake of ≥ 4 alcoholic beverages per day) • Subject has had prior prostatic surgery including TUNA, TURP, TUIP, laser treatment,

thermotherapy, balloon dilatation, prosthesis, and ultrasound ablation within 3 months of screening
- Participation in any investigational or marketed drug trial within 30 days prior to screening or anytime during the study period. This includes any interventional or exercise trials
- Any unstable serious co-existing medical condition(s) including, but not limited to, myocardial infarction, coronary bypass surgery, unstable angina, cardiac arrhythmias, clinically evident congestive heart failure, or cerebrovascular accident within 6 months prior to Screening visit
- Abnormal liver function test:

1-Total bilirubin > 1.8 X institutional upper limit of normal (ULN) 2-Aspartate aminotransferase (AST) > 1.8 X institutional ULN 3-Alanine aminotransferase (ALT) > 1.8 X institutional ULN 4-Alkaline phosphatase (ALP) > 1.8 X institutional ULN

- Serum creatinine > 1.8 X ULN
- History of other malignancies, with the exception of adequately treated nonmelanoma skin cancer, stage I melanoma, NMIBC or other solid tumors curatively treated with no evidence of disease for at least 5 years
- History or current evidence of substance abuse, as defined in DSM-IV, within 12 months of screening
- History of any illness (including psychiatric) that, in the opinion of the investigator, might confound the results of the study or pose additional risk to the subject
- No other concurrent metformin hydrochloride, sulfonylureas, thiazolidinediones, or insulin for any reason