

Titre	Surveillance de kystes rénaux complexes – Étude SOCRATIC
Protocole ID	SOCRATIC
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT04558593">NCT04558593</a>
Type(s) de cancer	Rein
Phase	Autres
Type étude	Autre
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Fred Saad
Coordonnateur	Amal Nadiri 514-890-8000 poste 26074
Statut	Actif en recrutement
Date d'activation	22-12-2022
But étude	One third of individuals aged >60 years will be diagnosed with at least one renal cyst following abdominal imaging. These cystic lesions are categorized according to the Bosniak classification which categorizes cysts according to their degree of complexity and risk of malignancy. Growing evidence suggests that a significant proportion of Bosniak III and IV cysts are benign and that the malignant ones present low metastatic potential. Since renal surgery carries substantial morbidity (20%) and potential mortality (0.5%), active surveillance has gained attention as a potential tradeoff to surgery to overcome overtreatment. Therefore, prospective studies of long-term follow-up are needed to confirm the oncologic safety of this strategy for patients with Bosniak III/IV cysts. This is an multicenter prospective observational longitudinal study. The main objective is to compare the 5-year follow-up cancer-specific survival between the active surveillance and the surgical groups.
Critères d'éligibilité	<ul style="list-style-type: none"> <li>• 18 years old and older;</li> <li>• diagnosed with a Bosniak III or IV cyst;</li> <li>• size of cystic component <math>\leq 7</math>cm;</li> <li>• cyst wall/septum nodule <math>&lt; 1</math>cm for Bosniak III cysts;</li> <li>• solid component <math>\leq 2</math> cm in maximal diameter for Bosniak IV cysts;</li> <li>• life expectancy <math>&gt; 5</math> years (by physician's estimate);</li> <li>• diagnosis <math>\leq 6</math> months from accrual date;</li> <li>• currently asymptomatic from the disease;</li> <li>• deemed fit enough for surgery;</li> <li>• willingness and ability to complete questionnaires in either French or English;</li> <li>• able and willing to provide informed consent</li> </ul>
Critères d'exclusion	<ul style="list-style-type: none"> <li>• history of a hereditary renal cancer syndrome;</li> <li>• presence of polycystic kidney disease;</li> <li>• any prior history of RCC;</li> <li>• received systemic therapy for another malignancy within the 12 months prior to accrual;</li> <li>• uncontrolled medical illness including infections, hypertension, arrhythmias, heart failure, or myocardial infarction/unstable angina within 6 months that would predispose to immediate surgical therapy;</li> <li>• metastatic disease or evidence of vascular or nodal disease;</li> <li>• unwillingness to undergo monitoring and imaging studies;</li> <li>• any contra-indication(s) to contrast-enhanced imaging (estimated glomerular filtration rate <math>&lt; 30</math>min/mL)</li> </ul>

- refusing to be co-enrolled in CKCis registry (when applicable in CKCis participating centers)