

Titre	Traitement de Canadiennes postménopausées atteintes d'un cancer du sein ER+ de stade avancé dans un contexte réel en association avec une hormonothérapie avec ou sans un traitement ciblé.
Protocole ID	CRAD001YCA09
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT02753686">NCT02753686</a>
Type(s) de cancer	Sein
Phase	Autres
Type étude	Autre
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Statut	Fermé
But étude	<p>Although randomized controlled trials (RCTs) provide evidence of efficacy, generalization of these results to patients in the real-world setting is challenging, given RCTs are conducted in highly selected patient populations. An understanding of the effectiveness and safety of approved cancer therapies in routine clinical practice is essential in order to optimize the management of these patients and to identify treatment and safety gaps. This is the first Canadian study to describe real-world treatment patterns/sequencing, effectiveness and safety for postmenopausal HR+ HER2- advanced breast cancer patients. This registry incorporates an observational prospective cohort design and will enroll 320 postmenopausal HR+ HER2- advanced breast cancer women that have been previously exposed to non-steroidal aromatase inhibitor (NSAI) therapy being treated with endocrine therapy (ET) or ET in combination with targeted therapy (TT).</p>
Critères d'éligibilité	<ul style="list-style-type: none"><li>• Patient has inoperable locally advanced or metastatic breast cancer.</li><li>• Patient has ER positive and/or PgR positive HER2-negative breast cancer by local laboratory testing (based on most recently analyzed biopsy).</li><li>• Patient is postmenopausal. Postmenopausal status is defined either by:<ul style="list-style-type: none"><li>• Prior bilateral oophorectomy</li><li>• Or age <math>\geq 60</math></li><li>• Or age <math>&lt; 60</math> and amenorrhea for 12 or more months (in the absence of chemotherapy, tamoxifen, toremifen, or ovarian suppression), and FSH and estradiol in the postmenopausal range (serum FSH <math>&gt; 40</math> mIU/mL and estradiol <math>&lt; 20</math> pg/mL or according to the postmenopausal range defined by local laboratory).</li></ul></li><li>• Patient has prior exposure to NSAI (letrozole or anastrozole) therapy in the adjuvant or metastatic setting. NSAI therapy does not have to be the last treatment prior to study entry. Other prior anticancer therapies, e.g. tamoxifen, fulvestrant are also allowed.</li><li>• Patient having received maximum one prior chemotherapy line for advanced/metastatic breast cancer is allowed.</li><li>• Patient currently receiving targeted therapy plus endocrine therapy (ET+TT) or endocrine therapy (ET) as per approved Health Canada indication or as per available expanded treatment protocol(s) or compassionate access program in either the 1st, 2nd or 3rd line advanced metastatic setting. Date of initiation of treatment should be a maximum of one month prior to the date of enrollment in this study. 1st, 2nd and 3rd line therapy in the advanced setting is defined as the first, second and third treatment respectively in the metastatic setting (which could include endocrine monotherapy, targeted therapy combination with endocrine therapy or chemotherapy).</li><li>• The decision to use ET or ET+TT has been reached prior to and independently of the current</li></ul>

	study.
Critères d'exclusion	<ul style="list-style-type: none"><li>• Patient receiving chemotherapy at baseline/study entry is excluded (however patient could have received up to one line of chemotherapy in the metastatic setting prior to study entry or as a subsequent therapy after completion of ET or ET+TT treatment).</li><li>• Patient having received more than 3 lines of systemic therapy in the metastatic setting.</li><li>• Patient is participating in a clinical trial for an investigational treatment with the exception of expanded treatment protocol or access program.</li><li>• Patient is undergoing any treatment that is not considered standard of care as per regional policies and guidelines with the exception of treatments accessed via expanded treatment protocols or access programs. This includes off-label use of any medications.</li></ul>