Essai Clinique

Généré le 29 mars 2024 à partir de

Titre	Essai de phase II, à répartition aléatoire, à double insu et contrôlé par placebo évaluant l'acide acétylsalicylique (ASA) dans la prévention du cancer de l'ovaire chez des femmes porteuses d'une mutation du gène BRCA1 ou BRCA2 (carcinome séreux tubaire intraépithélial tubaire [STIC] et néoplasme séreux tubaire occulte précoce [STONE])
Protocole ID	OV.25
ClinicalTrials.gov ID	NCT03480776
Type(s) de cancer	Ovaire
Phase	Phase II
Type étude	Prévention
Médicament	Acetylsalicylic Acid
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
Investigateur principal	Dr Paul Bessette
Coordonnateur	Annie Bourbonnais 819-346-1110 poste 12890
Statut	Fermé
Date d'activation	17-05-2018
But étude	While ASA is not a cancer medication, research suggests that taking ASA reduces the probability of getting many types of cancer because of its anti-inflammatory action. Inflammation in the ovaries during ovulation is thought to contribute to the development of ovarian cancer, and, because ASA is an anti-inflammatory medication, it may help to prevent it.
Critères d'éligibilité	• Previously documented germline BRCA1/2 pathogenic mutation or likely pathogenic variant based on the ACMG 2015 guidelines • Risk-reducing surgery (bilateral salpingo-oophorectomy or bilateral salpingectomy inclusive of fimbria) scheduled for within 6 months to 2 years after the date of randomization as standard of care, for women who have completed their families • ECOG performance status 0 or 1 • Age ≥ 18 years old • Subject is able (i.e. sufficiently literate) and willing to complete the Credibility/Expectancy questionnaire in English or French. • Subject consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each subject must sign a consent form prior to enrollment in the trial to document their willingness to participate • Subjects must be accessible for treatment and follow up. Subjects randomized on this trial must be treated and followed at the participating centre. • In accordance with CCTG policy, protocol treatment is to begin within 2 working days after subject randomization • Women of childbearing potential must have agreed to use a highly effective contraceptive method for the duration of the study treatment and for 30 days post last dose of study medication

Critères d'exclusion	• Subjects with history of other malignancies, except: • • adequately treated non-melanoma skin cancer; • curatively treated in-situ cancer of the cervix; • previously diagnosed (at any point) breast cancer, treated with curative intent; prior chemotherapy is allowed and the last dose must be ≥ 12 months prior to randomization; • other solid tumours curatively treated with no evidence of disease for > 5 years. • Subjects who have been treated with any PARP-inhibitors (e.g. olaparib) at any time. • Subjects with active bleeding or bleeding diathesis. • Subjects with active peptic ulcer. • Subjects with renal, hepatic or congestive heart failure. • Subjects with concurrent use of anti-coagulants. • Subjects with prior bilateral salpingectomy. • Subjects with history of chronic daily use of ASA or NSAIDs. • Subjects with intolerance of ASA including subjects with a history of asthma induced by salicylates or substances with a similar action, notably non-steroidal-anti-inflammatory drugs. • Ongoing or planned pregnancy. • Subjects who are breastfeeding.