# Essai Clinique

Généré le 07 mai 2024 à partir de

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| Titre | Essai randomisé, à double-insu, parallèle, contrôlé par placebo et multicentrique de phase III visant à évaluer l'efficacité et l'innocuité de l'Oliparib par rapport au placebo comme traitement adjuvant chez les patientes qui ont un cancer du sein primitif à mutation de la lignée germinale BRCA ½ et négatif pour le gène HER2 à risque élevé qui ont terminé un traitement local définitif et une chimiothérapie néoadjuvante ou adjuvante |
| Protocole ID | MA.36 |
| ClinicalTrials.gov ID | NCT02032823 |
| Type(s) de cancer | Sein |
| Phase | Phase III |
| Type étude | Traitement |
| Médicament | Olaparib |
| Institution | CHU DE QUEBEC – UNIVERSITE LAVAL<br>H HOPITAL DU SAINT-SACREMENT<br>1050 Ch Ste-Foy, Québec, QC, G1S 4L8 |
| Ville | Québec |
| Investigateur principal | Dre Christine Desbiens |
| Coordonnateur | Nathalie Carmichael<br>418-682-7511 poste 4551 |
| Statut | Fermé |
| Date d'activation | 20-07-2015 |
| But étude | Olaparib treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy |
| Critères d'éligibilité | • Histologically confirmed non-metastatic primary invasive adenocarcinoma of the breast that is one of the following phenotypes:<br>• Triple negative breast cancer defined as: ER and PgR negative AND HER2 negative (not eligible for anti-HER2 therapy)<br>• ER and/or PgR positive, HER2 negative<br>• Documented germline mutation in BRCA1 or BRCA2 that is predicted to be deleterious or suspected deleterious (known or predicted to be detrimental/lead to loss of function).<br>• Completed adequate breast and axilla surgery.<br>• Completed at least 6 cycles neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes or the combination of both. Prior platinum as potentially curative treatment for prior cancer (e.g. ovarian) or as adjuvant or neoadjuvant treatment for breast cancer is allowed.<br>• ECOG 0-1. |
| Critères d'exclusion | • Any previous treatment with a PARP inhibitor, including olaparib and/or known hypersensitivity to any of the excipients of study treatment.<br>• Patients with second primary malignancy. EXCEPTIONS are:<br>• adequately treated non-melanoma skin cancer, curatively treated in situ cancer of the cervix, Ductal Carcinoma in situ (DCIS) of the breast, stage 1 grade 1 endometrial carcinoma<br>• other solid tumours and lymphomas (without bone marrow involvement) diagnosed ≥ 5 years prior to randomisation and treated with no evidence of disease recurrence and for whom no more than one line of chemotherapy was applied.<br>• Concomitant use of known potent CYP3A inhibitors such as ketoconazole, itraconazole, |

ritonavir, indinavir, saquinavir, telithromycin, clarithromycin and nelfinavir
- Evidence of metastatic breast cancer