

**KURZPROTOKOLL**  
**OlympiA**

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| <b>Öffentlicher Titel</b>                        | Phase III Studie zu Olaparib als adjuvante Therapie bei BRCA-Mutation und Her2-negativem primären Brustkrebs mit hohem Risiko                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Wissenschaftl. Titel</b>                      | A Randomised, Double-blind, Parallel Group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Kurztitel</b>                                 | OlympiA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Studienart</b>                                | multizentrisch, Therapiestudie, randomisiert, doppelblind, zweiarmig, kontrolliert                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Studienphase</b>                              | Phase III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Erkrankung</b>                                | Geschlechtsorgane: Brustkrebs: adjuvant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Histologically confirmed non-metastatic primary triple negative invasive adenocarcinoma of the breast. •Invasive Triple Negative Breast Cancer</li><li>- Documented 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).</li><li>- Completed adequate breast and axilla surgery.</li><li>- Completed at least 6 cycles neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes or the combination of both. Prior platinum as potentially curative</li><li>- ECOG 0-1.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Any previous treatment with a PARP inhibitor, including olaparib and/or known hypersensitivity to any of the excipients of study treatment.</li><li>- Patients with second primary cancer, EXCEPTIONS: 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, or other solid tumours including lymphomas (without bone marrow involvement) curatively treated with no evidence of disease for 5 years prior to randomization. More than one course of chemotherapy for previous malignancies.</li><li>- Resting ECG with QTc &gt; 470 msec detected on 2 or more time points within a 24 hour period or family history of long QT syndrome. If ECG demonstrates QTc &gt;470 msec, patient will be eligible only if repeat ECG demonstrates QTc 470 msec.</li><li>- Concomitant use of known potent CYP3A4 inhibitors such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, telithromycin, clarithromycin and nelfinavir.</li><li>- Whole blood transfusions in the last 120 days prior to entry to the study which may interfere with gBRCA testing</li></ul> |
| <b>Alter</b>                                     | 18 Jahre und älter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Molekularer Marker</b>                        | BRCA<br>Triple neg (HER2/ER/PR neg)<br>HER2/neu neg./ER pos.<br>HER2/neu neg./PR pos.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Fallzahl</b>                                  | 1320                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Sponsor</b>                                   | Astra Zeneca                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Registrierung in anderen Studienregistern</b> | EudraCT 2013-003839-30<br>ClinicalTrials.gov NCT02032823                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |