KURZPROTOKOLL
OlympiA

Öffentlicher Titel	Phase III Studie zu Olaparib als adjuvante Therapie bei BRCA-Mutation und Her2-negativem primären Brustkrebs mit hohem Risiko
Wissenschaftl. Titel	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
Kurztitel	OlympiA
Studienart	multizentrisch, Therapiestudie, randomisiert, doppelblind, zweiarmig, kontrolliert
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: adjuvant
Einschlusskriterien	- Histologically confirmed non-metastatic primary triple negative invasive adenocarcinoma of the breast. •Invasive Triple Negative Breast Cancer - 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). - Completed adequate breast and axilla surgery. - Completed at least 6 cycles neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes or the combination of both. Prior platinum as potentially curative - ECOG 0-1.
Ausschlusskriterien	- Any previous treatment with a PARP inhibitor, including olaparib and/or known hypersensitivity to any of the excipients of study treatment. - 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. - Resting ECG with QTc > 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 >470 msec, patient will be eligible only if repeat ECG demonstrates QTc 470 msec. - Concomitant use of known potent CYP3A4 inhibitors such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, telithromycin, clarithromycin and nelfinavir. - Whole blood transfusions in the last 120 days prior to entry to the study which may interfere with gBRCA testing
Alter	18 Jahre und älter
Molekularer Marker	BRCA Triple neg (HER2/ER/PR neg) HER2/neu neg./ER pos. HER2/neu neg./PR pos.
Fallzahl	1320
Sponsor	Astra Zeneca
Registrierung in anderen Studienregistern	EudraCT 2013-003839-30 ClinicalTrials.gov NCT02032823