CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**PreCycle: Impact of eHealth-support on Quality of Life in metastatic breast cancer patients treated with Palbociclib and endocrine therapy**	
EudraCT-Nummer	**2016-004191-22**	
Sponsor	Palleos healthcare GmbH	
Prüfarzt	Prof. Dr. med. Cornelia Kolberg-Liedtke	
Kontakt Studienzentrale	An-schrift	Charité - Universitätsmedizin Berlin Campus Mitte Klinik für Gynäkologie CCM Virchowweg 20 Charitéplatz 1 10117 Berlin
	Tel.	+49 30 450 664 485
Kontakt Cancer-Hotline	+49 30 450 564 222 Email: cccc@charite.de	
Studienziel	To demonstrate superiority w.r.t. time to deterioration (TTD) of quality of life for patients with eHealth-based high density observation using CANKADO (CANKADO active) versus eHealth-based static observation on site (CANKADO inform).	
Behandlung	Palbociclib in combination with endocrine therapy (aromatase inhibitor or / Fulvestrant combined with a LHRH agonist in pre- or peri-menopausal women)	
Wichtigste Einschlusskriterien	1.Post- or pre/peri-menopausal female patients, age ≥18 years 2. Patients with metastatic or locally advanced (non-operable) breast cancer disease 3. Patients who are appropriate candidates for aromatase inhibitor + palbociclib combination therapy OR Patients having already received endocrine therapy who are appropriate candidates for fulvestrant+ palbociclib combination therapy: 4. Patient has not received treatment for locally advanced or metastatic disease OR Patient has received one prior line of chemotherapy and/or a maximum of two endocrine therapy lines for locally advanced or metastatic disease 5. Peri-/pre-menopausal patients should additionally receive a LHRH-agonist.. 6. The tumor must be hormone-receptor positive	

Wichtigste Einschlusskriterien	7. The tumor must be HER2-negative defined as either HER2 immunohistochemistry Score 0 or 1+ or as HER2-negative by ISH. 8. Eastern Cooperative Oncology Group (ECOG) performance status 0-2 9. Tissue of the primary tumor and metastatic lesion for biomarker study if applicable 10. Adequate organ and marrow function 11. In case of patients of child bearing potential: negative serum pregnancy test at baseline. Patients must agree to use highly effective non-hormonal contraception 12. Resolution of all acute toxic effects of prior therapy, including radiotherapy grade <1 (except toxicities not considered a safety risk for the patient) and recovery from surgical procedures 13. Signed Written Informed Consent 14. Willingness and capability to use CANKADO 15. Availability of hardware: Computer and/or tablet and/or smartphone with internet access