# *KURZPROTOKOLL*
# *PALLAS*

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| **Öffentlicher Titel** | Phase III Studie zu adjuvanter endokriner Therapie mit und ohne Palbociclib bei Her2-negativem, Hormonrezeptor-positivem Brustkrebs im Frühstadium |
| **Wissenschaftl. Titel** | PALbociclib CoLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+) / Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer (PALLAS) |
| **Kurztitel** | PALLAS |
| **Studienart** | multizentrisch, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig |
| **Studienphase** | Phase III |
| **Erkrankung** | Geschlechtsorgane: Brustkrebs: adjuvant |
| **Einschlusskriterien** | - Signed informed consent prior to study specific procedures.<br>- Age 18 years (or per national guidelines).<br>- Pre- and postmenopausal women or men with Stage II (Stage IIA limited to max. 1000 patients) or Stage III early invasive breast cancer<br>- Patients with multicentric and/or multifocal and/or bilateral early invasive breast cancer are eligible if all histopathologically examined tumors meet pathologic criteria for ER+ and/or PR+ and HER2-.<br>- Patients must have histologically confirmed ER+ and/or PR+, HER2-, early invasive breast cancer.<br>- Patients must have undergone breast surgery for the current malignancy. FFPE tumor tissue block must be confirmed to be received at the central sample repository prior to randomization.<br>- ECOG performance status 0-1.<br>- Patients must be able and willing to swallow and retain oral medication.<br>- Serum or urine pregnancy test must be negative in premenopausal women within 14 days of randomization, or in women with amenorrhea of less than 12 months at time of randomization.<br>- Serum or urine pregnancy test must be negative in premenopausal women within 14 days of randomization, or in women with amenorrhea of less than 12 months at time of randomization.<br>- Serum or urine pregnancy test must be negative in premenopausal women within 14 days of randomization, or in women with amenorrhea of less than 12 months at time of randomization.<br>- Serum or urine pregnancy test must be negative in premenopausal women within 14 days of randomization, or in women with amenorrhea of less than 12 months at time of randomization.<br>- Patients must either be initiating or have already started adjuvant hormonal treatment<br>- Patients who already received neo/adjuvant endocrine therapy are eligible as long as they are enrolled within 12 months of initial histological diagnosis and after completing no more than 6 months of adjuvant endocrine therapy.<br>- Absolute neutrophil count  1,500/µL<br>- Platelets  100,000/ mm3<br>- Hemoglobin  10g/dL<br>- Total serum bilirubin  ULN; or total bilirubin  3.0 × ULN with direct bilirubin within normal range in patients with documented Gilbert's Syndrome.<br>- Aspartate amino transferase (AST or SGOT) and alanine amino transferase (ALT or SGPT)  1.5 × institutional ULN.<br>- Serum creatinine within normal institutional limits or creatinine clearance  60 mL/min/1.73 m2 for patients with serum creatinine levels above institutional ULN. |

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| **Ausschlusskriterien** | - Concurrent therapy with other Investigational Products.<br>- Prior therapy with any CDK inhibitor.<br>- Patients with Stage I or IV breast cancer are not eligible.<br>- History of allergic reactions attributed to compounds of chemical or biologic composition similar to palbociclib.<br>- Patients receiving any medications or substances that are potent inhibitors or inducers of<br>- CYP3A isoenzymes within 7 days of randomization.<br>- Uncontrolled intercurrent illness that would limit compliance with study requirements.<br>- Pregnant women, or women of childbearing potential without a negative pregnancy test within 14 days prior to randomization.<br>- Patients with a history of any malignancy are ineligible (for exceptions see: Pallas<br>- Protocol, v1.0, Exclusion criteria 8).<br>- Patients who previously received endocrine therapy within 5 years prior to diagnosis of the current malignancy.<br>- Patients on combination antiretroviral therapy.<br>- Patients with clinically significant history of any liver disease.<br>- Patients receiving concurrent exogenous hormone therapy (topical vaginal estrogen therapy is allowable). |
| **Alter** | 18 Jahre und älter |
| **Molekularer Marker** | HER2/neu neg./ER pos.<br>HER2/neu neg./PR pos. |
| **Fallzahl** | 4600 |
| **Sponsor** | Alliance Foundation Trials, LLC. |
| **Förderer** | Alliance Foundation Trials, LLC. |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT02513394<br>EudraCT 2014-005181-30 |