KURZPROTOKOLL
AURORA

Öffentlicher Titel	Beobachtungsstudie mit dem Ziel, molekulare Aberrationen in metastasiertem Brustkrebs zu verstehen
Wissenschaftl. Titel	AURORA: Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer.
Kurztitel	AURORA
Studienart	multizentrisch, offen/unverblindet, einarmig
Erkrankung	Geschlechtsorgane: Brustkrebs: sonstige Studien für Brustkrebs
Ziele	- Metastatic Breast Cancer (MBC) understanding - To improve the understanding of MBC by performing high coverage Targeted Gene Sequencing (TGS) and RNA sequencing on matched primary and metastatic samples to explore tumor heterogeneity, clonal evolution and transcriptional changes associated with mutational and copy number variation (CNV) patterns. - Building new therapeutic hypotheses - Patients' prognosis determination - Identification of "exceptional responders" and "rapid progressors"; the outlier patients - Feasibility of implementing a global molecular screening platform for MBC - Correlation between molecular alterations and standardly assessed efficacy endpoints - Patient identification to match with biomarker-driven clinical trials
Einschlusskriterien	- Women or men with metastatic or locally relapsed breast cancer manageable with systemic therapy - Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1. - Written informed consent prior to enrollment into the program. - Patient aged 18 years - Patient agrees to provide archived primary tumor tissue - Patient agrees to provide newly collected metastatic lesions tissue samples (archived material up to 6 months is allowed provided both Formalin Fixed Paraffin Embedded (FFPE) block and Frozen Tissue are available and were collected from the same lesion at the same time) - Patient agrees to provide blood samples
Ausschlusskriterien	- The patient has received more than 1 line of systemic therapy (any type) in the metastatic setting - Patients who have received prior palliative radiotherapy to the only site that is accessible to biopsy - Patients with bone-only metastatic disease - Patients with brain-only metastatic disease, unless surgical excision is planned (in which case tissue will be collected for AURORA purpose) - Known presence of severe hematopoietic, renal, and/or hepatic dysfunction (according to the local PI) - Platelet count<100 000/mm3, INR>1.5 (international normalized ratio; blood clotting time) , Albumin<30 - Previous or current malignancies of other histologies within the last 5 years, with the exception of in situ carcinoma of the cervix, and adequately treated basal cell or squamous cell carcinoma of the skin - Any anti-VEGF (vascular endothelial growth factor) or anti-VEGFR (vascular endothelial growth factor receptor) treatment administered less than 4 weeks before new biopsy procedure or no appropriate wash-out period for patients on anticoagulation therapy
Alter	18 Jahre und älter

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Fallzahl	1300
Prüfzentren	**Sana Klinikum Offenbach** (Rekrutierung beendet) Ambulantes Onkologisches Zentrum Starkenburgring 66 63069 Offenbach n.a. Melanie Moschitz Tel: 069 8405 5815 Fax: 069 8405 4486 Melanie.Moschitz@sana.de
Sponsor	Breast International Group
Registrierung in anderen Studienregistern	Deutsches Register Klinischer Studien DRKS00007743 ClinicalTrials.gov NCT02102165