KURZPROTOKOLL
HerSCin

Öffentlicher Titel	Anwendungsbeobachtung zur subkutanen Gabe von Herceptin (Trastuzumab) bei Her2-positivem Brustkrebs im Frühstadium
Wissenschaftl. Titel	An Observational Study of Herceptin (Trastuzumab) Subcutaneous in Patients With HER2-Positive Early Beast Cancer
Kurztitel	HerSCin
Studienart	Anwendungsbeobachtung
Erkrankung	Geschlechtsorgane: Brustkrebs: Erstlinie
Ziele	- Pathological complete response (pCR) rate (for patients treated in the neo-adjuvant setting) [Time Frame: approximately 1 year] [Designated as safety issue: No] - Disease-free survival (DSF) rate after 2 years (for patients treated in the adjuvant setting) [Time Frame: 2 years] [Designated as safety issue: No] - Safety: Incidence of adverse events [Time Frame: up to 3 years] [Designated as safety issue: No] - Quality of life: EORTC QLQ-C30/QLQ-BR23 questionnaires [Time Frame: approximately 1 year] [Designated as safety issue: No] - Herceptin dose/treatment schedule/administration [Time Frame: approximately 1 year] [Designated as safety issue: No] - Concomitant chemotherapy/treatment/intervention [Time Frame: approximately 1 year] [Designated as safety issue: No]
Einschlusskriterien	- Female or male adult patient; >/= 18 years of age - Histologically confirmed adenocarcinoma of the breast - HER2-positive tumor - Eligible for neo-adjuvant or adjuvant treatment with Herceptin SC according to the judgement of the physician Note: As of patient recruitment (date of patient informed consent), retrospective documentation is allowed but limited to up to 9 weeks after initial start of therapy with Herceptin SC
Ausschlusskriterien	- Contraindications according to the Summary of Product Characteristics of Herceptin SC - Pregnant and breastfeeding women
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Fallzahl	960
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	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01959386