

KURZPROTOKOLL
Senomac

Öffentlicher Titel	Sentinel-Lymphknoten-Biopsie versus Axillakomplettierung
Wissenschaftl. Titel	Survival and Axillary Recurrence Following Sentinel Node-positive Breast Cancer Without Completion Axillary Lymph Node Dissection - a Randomized Study of Patients With Macrometastases in the Sentinel Node
Kurztitel	Senomac
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: sonstige Studien für Brustkrebs
Einschlusskriterien	- Patients with invasive breast cancer (T1-T3) - N0 on palpation - Preoperative ultrasound performed - Pathology report shows macrometastasis in 1-2 sentinel lymph nodes - Patients undergo breast-conserving therapy or mastectomy - The patient must have provided oral and written consent - Age $\geq$ 18 years
Ausschlusskriterien	- Metastases outside of the ipsilateral axilla - Prior history of invasive breast cancer - Pregnancy - Bilateral breast cancer if one side meets exclusion criteria - Medical contraindication for radiotherapy or systemic treatment - Inability to absorb or understand the meaning of the study information; for example, through disability, inadequate language skills or dementia.
Alter	18 Jahre und älter
Prüfzentren	Klinikum Hanau GmbH (Rekrutierung beendet) Klinik für Gynäkologie und Geburtshilfe Leimenstraße 20 63450 Hanau PD. Dr. med. Thomas Müller Tel: 06181 296-2500 Fax: 06181 296-2540 klinigyngeb@klinikum-hanau.de
Sponsor	AGO Studiengruppe
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02240472