

## **KURZPROTOKOLL** **Senomac**

<b>Öffentlicher Titel</b>	Sentinel-Lymphknoten-Biopsie versus Axillakomplettierung
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	Senomac
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Geschlechtsorgane: Brustkrebs: sonstige Studien für Brustkrebs
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Patients with invasive breast cancer (T1-T3)</li><li>- N0 on palpation</li><li>- Preoperative ultrasound performed</li><li>- Pathology report shows macrometastasis in 1-2 sentinel lymph nodes</li><li>- Patients undergo breast-conserving therapy or mastectomy</li><li>- The patient must have provided oral and written consent</li><li>- Age &gt;= 18 years</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Metastases outside of the ipsilateral axilla</li><li>- Prior history of invasive breast cancer</li><li>- Pregnancy</li><li>- Bilateral breast cancer if one side meets exclusion criteria</li><li>- Medical contraindication for radiotherapy or systemic treatment</li><li>- Inability to absorb or understand the meaning of the study information; for example, through disability, inadequate language skills or dementia.</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Prüfzentren</b>	<b>Klinikum Hanau GmbH</b> (Rekrutierung beendet) Klinik für Gynäkologie und Geburtshilfe Leimenstraße 20 63450 Hanau PD. Dr. med. Thomas Müller Tel: 06181 296-2500 Fax: 06181 296-2540 <a href="mailto:linikgynggeb@klinikum-hanau.de">linikgynggeb@klinikum-hanau.de</a>
<b>Sponsor</b>	AGO Studiengruppe
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT02240472