KURZPROTOKOLL
INSEMA

Öffentlicher Titel	Studie zur Behandlung von Brustkrebs im Frühstadium mit oder ohne SLN-Biopsie in der Achsel
Wissenschaftl. Titel	Comparison of Axillary Sentinel Lymph Node Biopsy Versus no Axillary Surgery in Patients With Early-stage Invasive Breast Cancer and Breast-conserving Surgery: a Randomized Prospective Surgical Trial. Intergroup-Sentinel-Mamma (INSEMA)-Trial
Kurztitel	INSEMA
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Investigator Initiated Trial (IIT), mehrarmig
Studienphase	nicht zutreffend
Erkrankung	Geschlechtsorgane: Brustkrebs: Erstlinie
Einschlusskriterien	- Written informed consent prior to beginning breast-conserving surgery, including expected cooperation of the patients for follow-up, must be obtained and documented according to the local regulatory requirements - Histologically confirmed unilateral primary invasive carcinoma of the breast (core biopsy). Multifocal tumors are allowed if breast-conserving surgery is planned - Age at diagnosis at least 35 years - Preoperative imaging techniques with estimated tumor size of <5 cm (iT1/iT2 irrespective of hormone sensitivity or HER2 status) - Clinically and sonographically tumor-free axilla prior to core biopsy (cN0/iN0) - In cases with cN0 and iN+, a negative core biopsy or fine needle aspiration (FNA) biopsy of the sonographically suspected lymph node is required before randomization - No clinical evidence for distant metastasis (M0) - Planned breast-conserving surgery (R0 resection) with postoperative external whole-breast irradiation (conventional fractionation or hypofractionation)
Ausschlusskriterien	- Secondary malignancy, except curatively treated basalioma of the skin and carcinoma in situ of the cervix - Time since core biopsy >3 months (optimal <1 month) - Previous and already (neoadjuvant) treated invasive breast carcinoma - Histologically non-invasive breast carcinoma - cT3/T4 or iT3/T4 tumors - Patients aged <35 years - Planned total mastectomy (e.g. multicentric tumors) - Planned intraoperative radiotherapy (e.g. Intrabeam) or postoperative partial breast irradiation (e.g. multicatheter technique) alone; both procedures are allowed as boost techniques - Male patients
Alter	35 Jahre und älter
Fallzahl	7095
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