

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	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- 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
Prüfzentren	Agaplesion Markus Krankenhaus (Nachbeobachtung) Wilhelm-Epstein-Straße 4 60431 Frankfurt am Main Madeleine Modrow Tel: 069 953366754 Fax: 069 95338916754 madeleine.modrow@fdk.info

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Main-Kinzig-Kliniken (Nachbeobachtung)

Herzbachweg 14
63571 Gelnhausen
Anita Sinsel
Tel: 06051 872448
Fax: 06051 872035
anita.sinsel@mkkliniken.de

Gudrun Riegel
Tel: 06051 872448
Fax: 06051 872035
gudrun.riegel@mkkliniken.de

Frauenheilkunde und Geburtshilfe (Nachbeobachtung)

Theodor-Stern-Kai 7
60590 Frankfurt am Main
Lena Schütz
Tel: 069 6301-84497
Fax: 069 6301-83655
lena.schuetz@kgu.de

Universitätsklinikum Frankfurt (Nachbeobachtung)

Klinik für Frauenheilkunde und Geburtshilfe
Theodor-Stern-Kai 7
60590 Frankfurt am Main
Lena Schütz
Tel: 069 6301-84497
Fax: 069 6301-83655
lena.schuetz@kgu.de

Klinikum Frankfurt Höchst (Nachbeobachtung)

Klinik für Gynäkologie und Geburtshilfe
Gotenstraße 6-8
65929 Frankfurt am Main
Prof. Dr. Joachim Rom
joachim.rom@varisano.de

Klinikum Hanau GmbH (Nachbeobachtung)

Klinik für Gynäkologie und Geburtshilfe
Leimenstraße 20
63450 Hanau
PD. Dr. med. Thomas Müller
Tel: 06181 296-2500
Fax: 06181 296-2540
linikgynggeb@klinikum-hanau.de

Sponsor

Universität Rostock

Förderer

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**Registrierung in anderen
Studienregistern**

ClinicalTrials.gov NCT02466737