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Integration of 3D-conformal, local radiotherapy (3DCRT) to metastatic sites in a paclitaxel weekly chemotherapy regimen in oligometastatic breast cancer patients: A phase I- and randomised phase II-study

Submission date 01/06/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 05/07/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/01/2021	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KKSH-14

Study information

Scientific Title
Integration of 3D-conformal, local radiotherapy (3DCRT) to metastatic sites in a paclitaxel weekly chemotherapy regimen in oligometastatic breast cancer patients: A phase I- and randomised phase II-study

Acronym
PACLITAXEL-3DCRT

Study objectives
Local 3D conformal radiotherapy to metastatic sites, provided in addition to systemic chemotherapy with paclitaxel weekly, improves progression-free-survival in patients with oligometastatic breast cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics information provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Metastatic breast cancer

Interventions
Chemotherapy with paclitaxel weekly in both groups with additional 3D conformal radiotherapy to metastatic sites in the experimental arm

Intervention Type
Other

Phase
Phase I/II

Primary outcome measure
Progression-free-survival in both study arms, as measured by the one-year progression free survival rate

Secondary outcome measures
1. Objective tumor response rate
2. Toxicity
3. Overall survival, as measured by 1-, 2-, and 3-year survival rates
4. Clinical benefit (defined as the proportion of patients with stable disease [SD] >24 weeks, complete response [CR] and partial response [PR])
5. Quality of life, as measured by European Organisation for Research and Treatment of Cancer (EORTC) quality of life questionnaires (QLQ) C30 and BR-23 in both study arms

Overall study start date
01/10/2005

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Women with histologically or cytologically confirmed, oligometastatic (stage IV) breast cancer, defined as: more than or equal to three metastatic lesions, or primary tumor and more than or equal to two metastatic lesions not amenable to curative surgery for medical or surgical reasons
2. Estrogen- and progesterone receptor negative status, hormone-refractory or rapid progressive disease
3. Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) (except patients with metastatic lesions confided to the bones who may be included in case of non-measurable, but assessasble disease
4. Age 18 to 75 years, Performance Status (PS) zero to one
5. Adequate renal, hematological and hepatic function
6. Minimum estimated life expectancy three months
7. Written informed consent
8. Absence of any condition potentially hampering compliance with the study protocol and follow-up schedule

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80 (phase II)

Key exclusion criteria
1. Patients with cerebral metastasis as well as metastasis in anantomic proximity to peripherapy nerves precluding the delivery of the planned radiochemotherapy
2. Malignant ascites, pericardial or pleural effusions
3. Concomitant malignancy (except basal cell skin carcinoma and carcinoma in situ of the uterine cervix)
4. Pregnant or lactating women, unclear contraception
5. Prior radiation to the metastatic sites
6. Prior treatment with taxanes
7. Known hypersensitivity to taxanes or cremophor EL
8. Patients with a history of grade III/IV peripheral neuropathy of any aetiology
9. Patients with diabetes mellitus and a peripheral neuropathy of any etiology

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
Germany

Study participating centre
Koordinationszentrum für Klinische Studien
Halle/Saale
Germany
06120

Sponsor information

Organisation
Martin-Luther-University (Germany)

Sponsor details

Universitätsplatz 10
Halle/Saale
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06108

Sponsor type
University/education

Website
http://www.verwaltung.uni-halle.de

ROR
https://ror.org/05gqaka33

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung) (BMBF) (grant no. 01ZP0301/G)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration