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Endocrine treatment with letrozole, with or without local 3D conformal radiotherapy (3DCRT) of metastatic lesions in postmenopausal patients with inoperable, hormone-sensitive, oligometastatic breast cancer: a multicentre, randomised phase II study

Submission date 01/06/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/07/2005	**Overall study status** Completed	
Last Edited 29/07/2014	**Condition category** Cancer	

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-13

Study information

Scientific Title

Acronym
LETROZOL-3DCRT

Study objectives
Local 3D conformal radiotherapy to metastatic sites, in addition to systemic treatment with letrozole, improves progression-free survival in postmenopausal, hormone-receptor positive patients with oligometastatic breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not 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
Inoperable, hormone-responsive, oligometastatic breast cancer

Interventions
Endocrine treatment with letrozole 2.5 mg po (orally) daily in both study arms, additional local 3DCRT (50 Gy) to metastatic lesions in the experimental arm

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Progression-free survival as measured by the one-year progression-free survival rate

Secondary outcome measures
1. Objective tumor response rate
2. Toxicity
3. 1-, 2-, 3-year survival rates
4. Clinical benefit (defined as 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

Overall study start date
01/10/2005

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Postmenopausal women with histologically or cytologically confirmed, oligometastatic breast cancer, defined as: ≤3 metastatic lesions, or primary tumor and ≤2 metastatic lesions not amenable to curative surgery for medical or surgical reasons
2. No prior endocrine therapy for metastatic disease
3. Estrogen receptor and/or progresterone receptor positive status or with both receptors unknown
4. Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) (except patients with metastatic lesions confined to the bones who may be included in case or non-measurable but assessable disease)
5. Age >18 years, Eastern Cooperative Oncology Group (ECOG) 0-2
6. Adequate hematological, renal and hepatic function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80

Key exclusion criteria
1. Central nervous system (CNS) metastasis or other metastasis in anatomic proximity to peripheral nerves precluding the delivery of the planned radiotherapy
2. Patients requiring immediate treatment with chemotherapy due to extensive visceral involvement or marked clinical symptoms
3. Malignant ascites, pericardial or pleural effusions, malignant infiltration of the bone marrow
4. Malabsorption syndrome or other uncontrolled medical conditions

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Germany

Study participating centre
Martin-Luther-University Halle-Wittenberg
Halle/Saale
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06120

Sponsor information

Organisation
Martin-Luther-University (Germany)

Sponsor details
Universitätsplatz 10
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06108

Sponsor type
University/education

Website
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