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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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

### Study type(s)
Treatment

### 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(s)
Progression-free survival as measured by the one-year progression-free survival rate

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### 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
Germany
06120

# Sponsor information

**Organisation**
Martin-Luther-University (Germany)

**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

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration