

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	☒ Prospectively registered ☐ Protocol
Registration date 05/07/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/07/2014	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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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 progesterone 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 of 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