

Trial of PeriOperative Endocrine Therapy - Individualising Care

Submission date 25/10/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/12/2007	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/03/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-a-short-course-of-hormone-therapy-before-and-after-surgery-for-early-breast-cancer>

(updated 31/03/2021, previously:

<http://www.cancerhelp.org.uk/trials/a-trial-of-a-short-course-of-hormone-therapy-before-and-after-surgery-for-early-breast-cancer>)

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2007-003877-21

IRAS number

ClinicalTrials.gov number

NCT02338310

Secondary identifying numbers

ICR-CTSU/2007/10015

Study information

Scientific Title

Trial of PeriOperative Endocrine Therapy - Individualising Care

Acronym

POETIC

Study objectives

1. That peri-operative endocrine therapy with an aromatase inhibitor for two weeks before and after surgery (perioperative therapy) followed by standard adjuvant therapy improves outcome compared with standard therapy alone in postmenopausal women with hormone receptor positive breast cancer
2. That the proliferation marker Ki67 as measured by Immunohistochemistry (IHC) in the excised cancer around 2 weeks after starting aromatase inhibitor therapy will predict for relapse free survival (Disease-Free Survival [DFS]) more effectively than the pre-treatment Ki67 value in the individual patient

Please note that as of 07/05/2008, the anticipated start and end dates of this trial were updated. The previous anticipated start and end dates were 01/02/2008 and 01/05/2011 respectively.

Please note that as of 10/10/2012, the anticipated end date for this trial was updated from 01/10/2011 to 01/02/2013

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Research Ethics Committee on 16/04/2008 (ref: 08/H1102/37).

Study design

Randomised phase III open-label clinical 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

Early breast cancer

Interventions

Patients will be randomised in the ratio of 2:1 to receive anastrozole 1 mg or letrozole 2.5 mg daily, taken orally for 4 weeks, commencing 2 weeks before surgery for primary breast cancer. Patients will be followed up long term, i.e., at least 5 years to satisfy primary endpoint of relapse free survival.

The Royal Marsden NHS Foundation Trust is a co-sponsor of this trial.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Anastrozole, letrozole

Primary outcome measure

Current primary outcome measures as of 11/10/2012:
Relapse free survival (clinical endpoint)

Previous primary outcome measures until 11/10/2012:

1. 5-year relapse free survival, planned for mid-2016
2. Proliferation rate (Ki67) at baseline core biopsy, and at surgical excision (both groups) to determine the relative accuracy of baseline and 2 week Ki67 in predicting outcome using pre-treatment and on-treatment values

Secondary outcome measures

Current secondary outcome measures as of 11/10/2012:

1. Time to local recurrence
2. Time to distant recurrence
3. Overall survival, planned for mid-2016
4. Gene expression profile at core biopsy and at surgical excision (both groups) to determine the relative accuracy of baseline and 2 week profiles in predicting outcome with pre-treatment and on-treatment
5. Proliferation rate (Ki67) at baseline core biopsy, and at surgical excision (biological endpoint)

Previous secondary outcome measures until 11/10/2012:

1. Time to local recurrence
2. Time to distant recurrence
3. Overall survival, planned for mid-2016

4. Gene expression profile at core biopsy and at surgical excision (both groups) to determine the relative accuracy of baseline and 2 week profiles in predicting outcome with pre-treatment and on-treatment

Overall study start date

01/08/2008

Completion date

01/08/2028

Eligibility

Key inclusion criteria

1. Postmenopausal women with core biopsy-proven hormone receptor positive invasive breast cancer. Postmenopausal is defined as a woman fulfilling any one of the following criteria:
 - 1.1. Aged greater than 50 years with amenorrhoea greater than 12 months and an intact uterus
 - 1.2. Has undergone a bilateral oophorectomy
 - 1.3. In women who have undergone a hysterectomy, then Follicle Stimulating Hormone (FSH) levels within the postmenopausal range (utilising ranges from the testing laboratory facility) are required if the patient is aged less than 55 years
 - 1.4. In women who have been on Hormone Replacement Therapy (HRT) within the last 12 months and therefore not amenorrhoeic, FSH levels within the postmenopausal range (utilising ranges from the testing laboratory facility) are required if the patient is aged less than 55 years
2. No evidence of metastatic spread by standard assessment according to local guidelines
3. Standard adjuvant endocrine therapy indicated
4. A palpable tumour of any minimum size, or a tumour with an ultrasound size of at least 1.5 cm
5. World Health Organization (WHO) performance status of 0, 1, or 2
6. Written informed consent to participate in the trial and to donation of tissue (fresh tissue and surplus tissue from diagnostic procedures)

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

4000

Key exclusion criteria

Current exclusion criteria as of 11/10/2012:

1. Locally advanced/inoperable breast cancer
2. Evidence of metastatic disease
3. Concurrent use of HRT
4. Prior endocrine therapy for breast cancer
5. Neoadjuvant chemotherapy
6. Any invasive malignancy within previous 5 years (other than basal cell carcinoma or cervical

carcinoma in situ)

7. Any severe coincident medical disease or inability to give informed consent
8. Treatment with a non-approved or investigational drug within 4 weeks before randomisation
9. Previous invasive breast cancer or bilateral breast cancer (surgically treated DCIS or LCIS allowed)
10. Previous use of oestrogen implants at ANY time
11. Continuous long term systemic steroid usage

Previous exclusion criteria until 11/10/2012:

1. Locally advanced/inoperable breast cancer
2. Evidence of metastatic disease
3. Concurrent use of HRT
4. Prior endocrine therapy for breast cancer
5. Neoadjuvant chemotherapy
6. Any invasive malignancy within previous 5 years (other than basal cell carcinoma or cervical carcinoma in situ)
7. Any severe coincident medical disease or inability to give informed consent
8. Treatment with a non-approved or investigational drug within 4 weeks before randomisation

Date of first enrolment

01/08/2008

Date of final enrolment

17/04/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Institute of Cancer Research

Sutton

United Kingdom

SM2 5NG

Sponsor information

Organisation

Institute of Cancer Research (UK)

Sponsor details

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United Kingdom
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R&D-CCR@rmh.nhs.uk

Sponsor type

Research organisation

Website

<http://www.icr.ac.uk/>

ROR

<https://ror.org/043jzw605>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C1491/A8671)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal in late 2019.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Jane Banerji (poetic-icrctsu@icr.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	interim results	31/12/2019	02/01/2019	Yes	No
Plain English results			31/03/2021	No	Yes