

Aromasin® randomised trial +/- Sutent® as neoadjuvant therapy for post-menopausal women with breast cancer

Submission date 14/11/2008	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/03/2009	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/10/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ARTiST version 1.0

Study information

Scientific Title

ARTiST: Aromasin® Randomised Trial +/- Sunitinib® as neoadjuvant Therapy for post-menopausal women with breast cancer

Acronym

ARTiST

Study objectives

Angiogenesis is important for the growth of all cancers and there is emerging evidence that angiogenesis inhibitors will be an important therapeutic option in breast cancers. The multi-targeted signal transduction inhibitor sunitinib has shown efficacy in advanced disease. Exemestane is a steroidal aromatase inhibitor commonly used.

Hypothesis: Simultaneous blockage of two important pathways will lead to a superior clinical response.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee, 30/12/2008, ref: 08/H0304/125

Study design

Phase II randomised open-label multi-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

The participants will be randomly allocated to the following two arms (randomisation ratio 1:1):
Arm A: Exemestane (Aromasin®) (oral) 25 mg/day for 18 weeks
Arm B: Exemestane (Aromasin®) (oral) 25 mg/day for 18 weeks + sunitinib (Sutent®) (oral) 37.5 mg/day for weeks 1 to 16, followed by a 2-week break before surgery

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Exemestane (Aromasin®), sunitinib (Sutent®)

Primary outcome measure

Ki67 response to therapy. Assessed by biopsy analysis pre-, during (week 3) and post-treatment (week 18)

Secondary outcome measures

1. Clinical response rate (cRR), assessed by clinical examination at weeks 3, 9 and 17
2. Radiological response rate (rRR), assessed by US scan at weeks 3, 9 and 17
3. Clinical/radiological response among patients over-expressing EGFR/HER-2, assessed by US scan/clinical examination at weeks 3, 9 and 17
4. Complete pathological response (pCR), assessed from the tumour tissue removed at surgery
5. Circulatory endothelial cells (CEC) and circulatory endothelial progenitor (CEP) levels, assessed by blood sample pre-, during (week 3) and post-treatment (week 18)
6. Analysis of candidate genes and global gene expression profiling to identify molecular markers of response or resistance. Assessed by biopsy analysis pre-, during (week 3) and post-treatment (week 18)
7. Disease free and overall survival. After surgery, patients will have a hospital visit every 6 months for 5 years

Overall study start date

01/03/2008

Completion date

28/02/2011

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

1. Females aged 50 to 80 years old
2. Ultrasound size: greater than 1 cm
3. Diagnosis of invasive breast cancer on core biopsy

4. Patients with localised, locally advanced invasive breast cancer
5. Histological grade: G1-3
6. Oestrogen Receptor (ER) positive (Allred score ≥ 4)

Participant type(s)

Patient

Age group

Senior

Sex

Female

Target number of participants

96

Key exclusion criteria

1. Previous history of cancer excluding basal cell carcinoma or cervical carcinoma in-situ
2. Previous deep vein thrombosis or pulmonary embolism
3. Uncontrolled hypertension
4. Any of the following within the 12 months prior to study drug administration: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft, symptomatic congestive heart failure, cerebrovascular accident or transient ischemic attack
5. Pre-existing thyroid abnormality with thyroid function that cannot be maintained in the normal range with medication
6. Ongoing cardiac dysrhythmias of \geq Grade 2 (National Cancer Institute [NCI] Common Terminology Criteria for Adverse Events (CTCAE) grading version 3.0), atrial fibrillation of any grade, or prolongation of the QTc interval >470 msec
7. Treatment with terfenadine, quinidine, procainamide, disopyramide, sotalol, probucol, bepridil, haloperidol, risperidone, ketoconazole or indapamide
8. Known HIV positive, or acquired immunodeficiency syndrome (AIDS) related illness

Date of first enrolment

01/03/2008

Date of final enrolment

28/02/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Oncology Department

Addenbrookes Hospital

Hills Road

Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

R&D Department
Box 277
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type

Hospital/treatment centre

Website

<http://www.addenbrookes.org.uk>

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Industry

Funder Name

Pfizer (Educational grant)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

No trial results – trial stopped after only one patient recruited

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No