ISRCTN11277575 https://doi.org/10.1186/ISRCTN11277575

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

Submission date 14/11/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/03/2009	**Overall study status** Stopped	
Last Edited 13/10/2017	**Condition category** Cancer	

Plain English Summary
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
ARTiST version 1.0

Study information

Scientific Title
ARTiST: Aromasin® Randomised TrIal +/- Sutent® as neoadjuvant Therapy for post-menopausal women with breast cancer

Acronym
ARTiST

Study hypothesis
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

Condition
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

Overall study end date
28/02/2011

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Participant 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

Participant 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 >= 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

Recruitment start date
01/03/2008

Recruitment end date
28/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oncology Department
Addenbrookes Hospital
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

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R&D Department
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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