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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 of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
Female

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 >= 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
United Kingdom

England

Study participating centre
Oncology Department
Addenbrookes Hospital
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (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, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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