

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

<b>Submission date</b> 14/11/2008	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/03/2009	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/10/2017	<b>Condition category</b> 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

Dr Helena Earl

### Contact details

Oncology Department  
Box 193  
Addenbrookes Hospital  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

## 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  $\geq 4$ )

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No