

# Comparing ARomatase Inhibition when given with or without SaracaTinib as an Advanced breast Cancer Therapy (ARISTACAT)

<b>Submission date</b> 29/11/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/03/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-saracatinib-post-menopausal-women-advanced-breast-cancer-aristacat>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

Version 1.0

## Study information

### Scientific Title

Comparing Aromatase Inhibition when given with or without Saracatinib as an Advanced breast Cancer Therapy (ARISTACAT): a randomised phase II study of aromatase inhibition with or without the src-inhibitor AZD0530 in post-menopausal women with advanced breast cancer

## **Acronym**

ARISTACAT

## **Study objectives**

1. Comparison of progression free survival between cohort receiving aromatase inhibition plus saracatinib, versus those receiving aromatase inhibition plus placebo
2. Toxicity, response rate and overall survival.

Translational sub-studies are also planned

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

National Research Ethics Service, West of Scotland, 6 December 2011, ref: 11/WS/0114

## **Study design**

Multi-centre placebo-controlled double-blind randomised phase II trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Advanced Breast Cancer

## **Interventions**

The patients will be allocated to a treatment using a minimisation algorithm. Stratification factors will be:

1. AI sensitivity strata
2. Disease site (bone metastases alone versus any other sites)
3. Bisphosphonate use
4. Performance status (0 v 1 v 2)
5. Treatment centre

Patients will be enrolled into one of two strata:

1. AI-sensitive/ naïve

These patients will have potentially AI-sensitive tumours

Treatment = anastrozole 1mg daily + saracatinib 175 mg daily OR exemestane 25mg daily + saracatinib 175 mg daily

2. Prior-AI

These patients will have cancers which have already progressed on an AI, but for whom there is

likely to still be some endocrine sensitivity

Treatment = anastrozole 1mg daily + placebo daily OR exemestane 25mg daily + placebo daily

Saracatinib (AZD0530) is an oral src inhibitor and can be administered with or without food. The choice of either anastrozole or exemestane is driven by what would be an acceptable standard therapy for the patient, and then the patients are randomised to either get saracatinib or placebo.

### **Intervention Type**

Drug

### **Phase**

Phase II

### **Drug/device/biological/vaccine name(s)**

Anastrozole, exemestane, saracatinib

### **Primary outcome(s)**

Current primary outcome measure as of 02/04/2019:

Progression free survival will be measured using time to progression through standard, regular, clinical assessment.

Previous primary outcome measure:

1. Progression free survival
2. Time to progression will be measured through standard, regular, clinical assessment

### **Key secondary outcome(s)**

1. Toxicity
2. Change in tumour size analysed using a Waterfall plot in the two strata separately
3. Overall survival

### **Completion date**

31/03/2017

## **Eligibility**

### **Key inclusion criteria**

1. Females who are clearly post menopausal with Estrogen Receptor (ER) positive (Allred score  $\geq$  3) advanced breast cancer with at least one lesion which is measurable. They may also have additional evaluable but non-measurable lesions.
2. Patients must be performance status 0-2
3. Suitable for treatment with an aromatase inhibitor
4. Life expectancy > 3 months
5. Cancer must be HER2- (by FISH and/or IHC as appropriate), OR if the cancer is HER2+ the patient must not be a candidate for anti-HER2 therapy
6. All patients will need to also meet inclusion criteria for one of the two main strata:
  - 6.1. AI-sensitive/naive group either never previously treated with an aromatase inhibitor, but if treated with tamoxifen must not have rapid progression on tamoxifen (i.e. treated for at least 24 months adjuvant or  $\geq$  6 months in metastatic setting); or, if previously treated with an AI, only in the adjuvant or neo-adjuvant setting AND have remained free of progression for at least 12 months whilst not being treated with an AI

- 6.2. Prior AI group patients NOT meeting the criteria in 6.1 (above), but previously treated with a non-steroidal AI without progression for at least 24 months in the (neo-) adjuvant setting or for at least 6 months for advanced disease
7. Patients who have had two lines of prior AI therapy will not be eligible UNLESS they were switched from one AI to another ONLY for reasons of toxicity, and ONLY during (neo-) adjuvant therapy AND in the absence of any evidence of progression/relapse
8. Single site of bone disease must be histologically confirmed and known not to be ER negative
9. Palliative radiotherapy can be given to bone lesions within 4 weeks of trial entry provided not more than 20% of the bone marrow is irradiated, AND there is at least one other measurable bone lesion which has clearly progressed since any prior irradiation
10. Haematology commensurate with a phase II hormonal therapy study: Neutrophils  $> 1.5 * 10^9$  /l, Hb  $> 10.0$  g/dl and Platelets  $> 100 * 10^9$  /l
11. Biochemistry similar: albumin normal, ALT/AST  $< 2.5$  ULN, Alk Phos  $< 5 * ULN$  unless of bone origin, e-GFR  $> 50$ ml/min
12. Normal urea & electrolytes
13. Patients receiving bisphosphonates are eligible, provided they are commenced before, or at, trial entry
14. Patients will be stratified by use of, or stated intention to give, bisphosphonate at randomisation
15. Patients ideally should have been on therapy for at least 1 week before starting trial therapy, but must start within 1 week after starting trial therapy

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Total final enrolment**

140

### **Key exclusion criteria**

1. Patients with short life expectancy or significant other co-morbidity including pulmonary fibrosis
2. Rapidly progressive visceral disease (lymphangitis, diffuse liver disease, uncontrolled CNS disease)
3. Resting ECG with a measureable QTc  $> 480$  msec
4. Any evidence of severe or uncontrolled systemic conditions (e.g. interstitial lung disease [bilateral, diffuse, parenchymal change])
5. Life expectancy  $< 3$  months
6. Contra-indication to either AZD0530 (or excipients) or aromatase inhibition
7. Concomitant chemotherapy or anti-HER2 therapy

### **Date of first enrolment**

01/03/2012

**Date of final enrolment**

31/03/2017

## Locations

**Countries of recruitment**

United Kingdom

Scotland

**Study participating centre**

**Edinburgh Cancer Centre**

Edinburgh

United Kingdom

EH4 2XU

## Sponsor information

**Organisation**

The Common Services Agency (UK)

**ROR**

<https://ror.org/04za2st18>

## Funder(s)

**Funder type**

Industry

**Funder Name**

AstraZeneca (UK)

**Alternative Name(s)**

AstraZeneca PLC, Pearl Therapeutics, AZ

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		02/03/2023	02/03/2023	Yes	No
<a href="#">Basic results</a>		20/03/2019	02/04/2019	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			09/07/2019	No	Yes