ISRCTN23804370 https://doi.org/10.1186/ISRCTN23804370

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

Submission date 29/11/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/01/2012	**Overall study status** Completed	
Last Edited 02/03/2023	**Condition category** Cancer	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 inhibitionwith 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

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 below to request a patient information sheet

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 with have potentially AI-sensitive tumours
Treatment = anastrazole 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 = anastrazole 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 anastrazole 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)
Anastrazole, exemestane, saracatinib

Primary outcome measure
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

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

Overall study start date
01/03/2012

Completion date
31/03/2017

Eligibility

Key inclusion criteria

1. Females who are clearly post menopausal with Estrogen Receptor (ER) positive (Allred score ≥ 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 ant-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 ≥ 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 * 109 /l, Hb> 10.0 g/dl and Platelets > 100 * 109/l
11. Biochemistry similar: albumin normal, ALT/AST < 2.5 ULN, Alk Phos < 5 * ULN unless of bone origin, e-GFR > 50ml/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

Age group

Adult

Sex

Female

Target number of participants

140 patients will be recruited over a 2 year period at around 20 sites in the UK

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
Scotland

United Kingdom

Study participating centre
Edinburgh Cancer Centre
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
The Common Services Agency (UK)

Sponsor details
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Sponsor type
Government

Website
http://www.nhsnss.org/

ROR
https://ror.org/04za2st18

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca (UK)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

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