

# A randomised trial of sequential aromatase inhibitors (AI) in postmenopausal women with locally advanced or metastatic breast cancer

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| <b>Submission date</b><br>19/08/2002   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>19/08/2002 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>18/01/2016       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/sequential-aromatase-inhibitors-in-postmenopausal-women-with-breast-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

Dr - -

### Contact details

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## Additional identifiers

### Protocol serial number

C/15/00

## Study information

### Scientific Title

A randomised trial of sequential aromatase inhibitors (AI) in postmenopausal women with locally advanced or metastatic breast cancer

**Acronym**

SAINT

**Study objectives**

Not provided at time of registration

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Breast cancer

**Interventions**

In the experimental arms of the study (A1 and A2) patients will initially receive a second generation AI (in the form of Formestane, 250 mg im 2-weekly) followed at disease progression by a third generation AI, which by randomisation will be either (A1) non steroidal (Anastrozole 1 mg po daily) or (A2) steroidal (Exemestane 25 mg po daily).

Patients in the control arms of the study (B1 and B2) will receive immediate Anastrozole 1 mg po daily (B1) or Exemestane 25 mg po daily (B2).

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Formestane, anastrozole, exemestane

**Primary outcome(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/12/2004

## Eligibility

**Key inclusion criteria**

1. Patients with positive estrogen receptor (ER) and/or progesterone receptor (PgR) status
2. Postmenopausal
3. Measurable or accessible locally advanced, unresectable or locoregionally recurrent or metastatic breast carcinoma with documented disease progression
4. At least one bidimensionally measurable lesion should be available for assessment
5. Patients would have failed to respond to previous first line treatment with anti-oestrogens

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Female

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2001

**Date of final enrolment**

31/12/2004

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

# Sponsor information

## Organisation

International Collaborative Cancer Group (ICGG) (UK)

## Funder(s)

### Funder type

Research organisation

### Funder Name

International Collaborative Cancer Group (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration