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

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>18/01/2016 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] 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**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### 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
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 (Anastrazole 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 Anastrazole 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, anastrazole, exemestane

### Primary outcome measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/2001

### 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

### Age group
Not Specified

### Sex
Female

### Target number of participants
Not provided at time of registration

### 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
England

United Kingdom

### Study participating centre
**MRC Clinical Trials Unit**
London
United Kingdom
NW1 2DA

# Sponsor information

### Organisation
International Collaborative Cancer Group (ICGG) (UK)

### Sponsor details
Medical Oncology
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

### Sponsor type
Research organisation

# Funder(s)

### Funder type
Research organisation

### Funder Name
International Collaborative Cancer Group (UK)

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration