

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

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/01/2016	Condition category 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

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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