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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	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/01/2016	**Condition category** Cancer	[_] Individual participant data [_] 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
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

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 (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(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