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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
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

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 hypothesis
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

Condition
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

Overall study end date
31/12/2004

Eligibility

Participant 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

Participant exclusion criteria
Not provided at time of registration

Recruitment start date
01/01/2001

Recruitment end date
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