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A Randomised Double-Blind, Double Dummy Trial to Compare the Efficacy and Safety of Arimidex with Tamoxifen as First line Therapy for Advanced Breast Cancer in Post-Menopausal Women

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 28/11/2019	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZEN1033IL/27

Study information

Scientific Title
A Randomised Double-Blind, Double Dummy Trial to Compare the Efficacy and Safety of Arimidex with Tamoxifen as First line Therapy for Advanced Breast Cancer in Post-Menopausal Women

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 Double-Blind Double Dummy Trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
1. Group A: Arimidex (anastrozole) 1 mg plus tamoxifen placebo daily
2. Group B: Tamoxifen 20 mg plus Arimidex placebo daily

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Arimidex with Tamoxifen

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

Completion date
01/07/1998

Eligibility

Key inclusion criteria
1. Patients with locally advanced or metastatic breast cancer who are candidates to receive hormonal therapy as first line therapy for advanced disease (patients may have received adjuvant chemotherapy or hormonal therapy but patients who have received tamoxifen as adjuvant therapy must have an interval of at least 12 months since stopping tamoxifen and entry into this trial)
2. Post-menopausal defined as:
2.1 Aged >50 years or who have not menstruated during the preceding 12 months or who have follicle-stimulating hormone (FSH) levels within the post-menopausal range
2.2 Women aged <50 years who have FSH levels within the post-menopausal range
3. Hormone receptor (oestrogen receptor and or progesterone receptor) positive or unknown
4. Measurable or evaluable disease
5. No previous systemic therapy for advanced breast cancer
6. No drug-maintained menopausal status
7. No evidence of life threatening visceral disease
8. Life expectancy of >3 months
9. No treatment with a non-approved or experimental drug within the preceding 3 months before randomisation
10. No prior history of other malignancy other than breast cancer, except basal cell or squamous cell carcinoma of the skin or cancer of the cervix which has been satisfactorily controlled
11. No contraindications to protocol treatments

Participant type(s)
Patient

Age group
Adult

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
01/01/1996

Date of final enrolment
01/07/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
AstraZeneca Clinical Research Group (UK)

Sponsor details
10 Logie Mill
Beaverbank Office Park
Lovie Green Road
Edinburgh
United Kingdom
EH7 4HG

Sponsor type
Industry

Website
http://www.astrazeneca.co.uk

ROR
https://ror.org/04r9x1a08

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca Pharmaceuticals (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