# 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	Recruitment status	Prospectively registered
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	[] Individual participant data
28/11/2019	Cancer	<ul><li>Record updated in last year</li></ul>

# **Plain English summary of protocol**Not provided at time of registration

#### 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

**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