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A randomised double-blind trial comparing arimidex alone with nolvadex alone with arimidex and nolvadex in combination, as adjuvant treatment in post-menopausal women with 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 [X] Results
Last Edited 06/04/2017	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-comparing-anastrozole-and-tamoxifen-after-surgery-for-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZEN1033IL/29

Study information

Scientific Title
A randomised double-blind trial comparing arimidex alone with nolvadex alone with arimidex and nolvadex in combination, as adjuvant treatment in post-menopausal women with breast cancer

Acronym
ATAC (Arimidex, Tamoxifen, Alone or in Combination)

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 controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions

1. Group A: Arimidex (anstrozole) 1 mg plus Nolvadex (tamoxifen) placebo both daily for 5 years or until recurrence
2. Group B: Arimidex 1 mg plus Nolvadex 20 mg, both daily for 5 years or until recurrence
3. Group C: Arimidex placebo plus Nolvadex 20 mg, both daily for 5 years or until recurrence

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1998

Completion date
01/12/1999

Eligibility

Key inclusion criteria
1. Histologically proven operable breast cancer
2. Patients must have completed primary surgery and chemotherapy (if given), and are candidates to receive hormonal adjuvant therapy
3. Deemed to be post-menopausal according to one of the following:
3.1. Aged >60 years
3.2. Bilateral oophorectomy
3.3. Aged <60 years with a uterus and amenorrhoea for at least 12 months
3.4. Aged <60 without a uterus and with follicle stimulating hormone (FSH) >20IU/L
4. No evidence of metastatic disease
5. If chemotherapy was started more than 8 weeks after primary surgery or chemotherapy was completed more than 8 weeks before randomisation the patients is excluded
6. No neo-adjuvant chemotherapy
7. Surgery must have been completed within 8 weeks prior to randomisation
8. No previous hormonal therapy as adjuvant treatment for breast cancer unless:
8.1. Tamoxifen received prior to first surgical procedure for 28 days or less
8.2. Hormonal therapy received pre-surgery in the context of a formal trial
9. Patients who have received tamoxifen as part of any breast cancer prevention trial are to be excluded
10. No previous malignancy within the last 10 years, except squamous or basal cell carcinoma of the skin or carcinoma in situ of the cervix, adequately cone biopsied
11. No treatment with a non-approved drug during the 3 months before randomisation
12. No medical contraindications to any of the treatments in the trial

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/01/1998

Date of final enrolment
01/12/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
ATAC secretariat
London
United Kingdom
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2005		Yes	No
Results article	results of long-term safety analysis	01/08/2006		Yes	No
Results article	results on 10 year analysis of trial	23/11/2007		Yes	No
Results article	results of 100-month analysis	01/01/2008		Yes	No
Results article	five year results	01/03/2008		Yes	No
Results article	results on the effect of body mass index on recurrence rates	20/07/2010		Yes	No
Results	results				

article		01/12/2010	Yes	No
Results article	results	04/04/2012	Yes	No