ISRCTN17222211 https://doi.org/10.1186/ISRCTN17222211

Adjuvant Tamoxifen Treatment - offer more? To assess reliably the balance of benefits and risks of prolonging adjuvant tamoxifen treatment by 5 years for women with breast cancer

Submission date 22/03/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/03/2001	**Overall study status** Completed	
Last Edited 23/10/2020	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/tamoxifen-for-early-stage-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003678

Secondary identifying numbers
BR3009

Study information

Scientific Title
Adjuvant Tamoxifen Treatment - offer more? To assess reliably the balance of benefits and risks of prolonging adjuvant tamoxifen treatment by 5 years for women with breast cancer

Acronym
aTTom

Study objectives
To assess reliably, the balance of benefits and risks of prolonging adjuvant tamoxifen treatment by 5 years, in women with early breast cancer

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

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

Interventions
Group A - No further treatment with tamoxifen
Group B - At least 5 years further treatment with tamoxifen

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tamoxifen

Primary outcome measure
To detect or refute reliably any overall survival benefit from extending the duration of therapy with adjuvant tamoxifen

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1994

Completion date
01/08/2014

Eligibility

Key inclusion criteria
1. Any woman who has had complete excision of breast carcinoma
2. Any primary treatment
3. At least 2 years of prior adjuvant tamoxifen treatment (5 recommended)
4. Clinically relapse free
5. No definite indications or contraindications for further tamoxifen treatment: uncertainty as to whether further tamoxifen treatment will be of benefit
6. Where possible, ER status should be known prior to randomisation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
8000

Total final enrolment
6953

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1994

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Clinical Trials Unit
Birmingham
United Kingdom
B15 2RR

Sponsor information

Organisation
The University of Birmingham (UK)

Sponsor details
Edgbaston
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England
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-
abc@123.com

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Medical Research UK (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2013 results presented at ASCO http://ascopubs.org/doi/abs/10.1200/jco.2013.31.18_suppl.5

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?
Plain English results				No	Yes
Results article	results	01/11/2019	23/10/2020	Yes	No