

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
Registration date 22/03/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/10/2020	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/tamoxifen-for-early-stage-breast-cancer>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00003678

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Birmingham Clinical Trials Unit
Birmingham
United Kingdom
B15 2RR

Sponsor information

Organisation

The University of Birmingham (UK)

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, Cancer Research UK (CRUK), 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2019	23/10/2020	Yes	No
Plain English results				No	Yes