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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

Registration date
22/03/2001

Last Edited
23/10/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Mr Martin J Lee

Contact details
Birmingham Clinical Trials Unit
University of Birmingham
Park Grange, 1 Somerset Road
Edgbaston
Birmingham
United Kingdom
B15 2RR

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

Study design
Randomised controlled trial

Primary study design
Interventional

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