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Scottish Pre-Menopausal Chemo-Endocrine Trial

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002580

Secondary identifying numbers
BR9401

Study information

Scientific Title
-

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)
Not Specified

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

Interventions
Following surgery patients are randomised to one of four treatment arms:
1. Group A: Tamoxifen 20 mg daily for 5 years
2. Group B: Tamoxifen 20 mg daily for 5 years plus six cycles of CMF (cyclophosphamide, methotrexate, 5-fluorouracil) chemotherapy
3. Group C: Tamoxifen 20 mg daily for 5 years plus ovarian suppression
4. Group D: Tamoxifen 20 mg daily for 5 years, six cycles of CMF chemotherapy and ovarian suppression

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Tamoxifen

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1993

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Histologically confirmed invasive carcinoma of the breast
2. Pre-menopausal
3. No medical contraindications to treatment

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1000

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/1993

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Scottish Cancer Therapy Network (UK)

Sponsor details
Trinity Park House
South Trinity Road
Edinburgh
United Kingdom
EH5 3SQ

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Scottish Cancer Therapy Network (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	01/01/1999	14/02/2019	Yes	No