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Clinical trial of six versus three courses of cyclophosphamide, methotrexate and 5-fluorouracil adjuvant chemotherapy in the treatment of pre-menopausal women with carcinoma of the breast

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 01/07/2001	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 21/11/2019	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BR305

Study information

Scientific Title
Clinical trial of six versus three courses of cyclophosphamide, methotrexate and 5-fluorouracil adjuvant chemotherapy in the treatment of pre-menopausal women with carcinoma of the breast

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)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
All patients receive surgery followed by:
1. Group A: Chemotherapy, cyclophosphamide, methotrexate and 5-fluorouracil (CMF) repeated every 4 weeks for three cycles.
2. Group B: Chemotherapy, cyclophosphamide, methotrexate and 5-fluorouracil (CMF) repeated every 4 weeks for six cycles.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Cyclophosphamide, methotrexate and 5-fluorouracil

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1994

Completion date
19/09/1996

Eligibility

Key inclusion criteria
1. Histologically proven invasive carcinoma of the breast
2. Aged <50 years
3. Axillary node positive with less than ten positive nodes, or node negative and deemed to be high risk: Grade 3; Grade 2 and tumour >2 cm; Grade 1 and tumour >5 cm
4. No evidence of distant metastases
5. No other malignancy, other than basal cell carcinoma or in situ cervical cancer or any malignancy with a similar prognosis
6. No previous chemotherapy
7. No contraindications to treatment protocols

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1994

Date of final enrolment
19/09/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research 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

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