

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

Dr - -

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary