

# 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

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| <b>Submission date</b><br>01/07/2001   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>01/07/2001 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>21/11/2019       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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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## 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