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A Study Comparing CMF (Cyclophosphamide, Methotrexate, 5-fluorouracil) and MMM (Mitozantrone, Methotrexate, Mitomycin-C) Chemotherapy in Patients with Metastatic Breast Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 07/04/2015	**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
- -

Contact details
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Additional identifiers

Protocol serial number
C90

Study information

Scientific Title
A Study Comparing CMF (Cyclophosphamide, Methotrexate, 5-fluorouracil) and MMM (Mitozantrone, Methotrexate, Mitomycin-C) Chemotherapy in Patients with Metastatic Breast Cancer

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
Patients will be randomised to one of the following:

1. CMF Regimen: Chemotherapy with CMF (cyclophosphamide, methotrexate, 5-fluorouracil), a maximum of six cycles. Folinic acid to be given every 6 h for four doses commencing 24 h after chemotherapy.

2. MMM Regimen: Chemotherapy, MM (mitozantrone, methotrexate) alternating with MMM (mitozantrone, methotrexate, mitomycin-C), a maximum of six cycles in total. Folinic acid to be given every 6 h for four doses commencing 24 h after chemotherapy.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CMF (cyclophosphamide, methotrexate, 5-fluorouracil), MM (mitozantrone, methotrexate), MMM (mitozantrone, methotrexate, mitomycin-C)

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Histologically proven breast cancer, metastatic or incurable locally recurrent disease
2. No other malignancy except adequately treated in situ carcinoma of cervix or non melanomatous skin cancer
3. Previous adjuvant chemotherapy or neo-adjuvant chemotherapy is acceptable, unless the disease free interval is <2 years following adjuvant CMF chemotherapy
4. Previous chemotherapy for metastatic disease is acceptable
5. Patients must be willing to complete quality of life questionnaire and be interviewed by a senior nurse
6. Normal liver function
7. Patients must be considered fit enough to receive either standard CMF or MMM chemotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients are not eligible if they are eligible for a first line phase II study. Patients may become eligible at the time of progression
2. Patient are not eligible if they present with immediately life threatening disease for whom the physician considers an anthracycline based combination preferable

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2005

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