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A randomised trial to evaluate a loading dose of medroxyprogesterone acetate with two different maintenance schedules in patients with advanced breast cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 17/02/2015	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BR3007

Study information

Scientific Title
A randomised trial to evaluate a loading dose of medroxyprogesterone acetate with two different maintenance schedules in patients with advanced 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

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 cancer

Interventions
Patients are randomised to one of four treatment groups:
1. Group A: Loading dose medroxyprogesterone acetate (MPA), 1 g every 6 h for eight doses, followed by low dose maintenance 500 mg MPA daily
2. Group B: Low dose maintenance, 500 mg MPA daily
3. Group C: Loading dose MPA, 1 g every 6 h for eight doses, followed by high dose maintenance, 1000 mg MPA daily
4. Group D: High dose maintenance, 1000 mg MPA daily

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medroxyprogesterone acetate

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1998

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Histologically proven advanced or metastatic disease
2. Measurable or assessable disease
3. Previously treated with tamoxifen resulting in relapse or no response
4. No previous therapy with medroxyprogesterone acetate (MPA) or other progesterones
5. No anti-cancer therapy within the preceding 4 weeks, but patients who, having stopped prior therapy show evidence of disease progression during the 4th week interval between treatments may enter the trial forthwith
6. Able to tolerate 8 weeks hormonal therapy
7. No evidence of brain metastases
8. No pre-existing malignancy, except non-melanomatous skin cancer

Participant type(s)
Patient

Age group
Not Specified

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
01/01/1998

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
-

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
222 Euston Road
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Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Not defined

Funder Name
Not available

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