

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	<input type="checkbox"/> Prospectively registered
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/02/2015	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<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

Contact details

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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
London
United Kingdom
NW1 2DA

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