

Comparison of second-line hormonal agents medroxyprogesterone acetate and aminoglutethimide in advanced breast cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/01/2015	Condition category Cancer	<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
BR3004

Study information

Scientific Title

Comparison of second-line hormonal agents medroxyprogesterone acetate and aminoglutethimide in 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)

Treatment

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 receive either:

1. Group A: Medroxyprogesterone acetate 250 mg four times daily until disease progression or failure of treatment.
2. Group B: Aminoglutethimide 250 mg twice daily plus hydrocortisone 20 mg twice daily until disease progression or failure of treatment. There is a crossover option on disease progression or failure of treatment.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Medroxyprogesterone acetate, aminoglutethimide, hydrocortisone

Primary outcome measure

Not provided at time of registration.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/08/1991

Completion date

01/08/1996

Eligibility

Key inclusion criteria

1. Advanced breast cancer
2. Relapsed or failed following tamoxifen treatment
3. Postmenopausal

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/1991

Date of final enrolment

01/08/1996

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Ciba-Geigy Pharmaceuticals (Switzerland)

Sponsor details

-
-

Switzerland

-

Sponsor type
Industry

ROR
<https://ror.org/02f9zrr09>

Funder(s)

Funder type
Industry

Funder Name
Ciba-Geigy Pharmaceuticals, Farmitalia Carlo Erba

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