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

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 27/01/2015	**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
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