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Randomised phase II trial comparing vinorelbine and capecitabine with docetaxel and capecitabine chemotherapy for metastatic breast cancer

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 29/10/2012	**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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0205108870

Study information

Scientific Title

Study objectives
Toxicity, response and survival.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Randomisation will be stratified by previous anthracycline exposure.
1. Vinorelbine 25mg/m^2 intravenous (IV) 30 min DI + 8q 21 days. Capecitabine 1 g/m^2 orally, twice daily for 14 in every 21 days.
2. Docetaxel 75 mg/m^2 IV 60 min every 21 days with dexamethasone 8 mg twice daily for three days starting 24 hours before each docetaxel treatment. Capecitabine 1 g/m^2 orally, twice daily for 14 in every 21 days.

Added 17 July 2008: the trial closed in 2006 due to poor recruitment.

Intervention Type

Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Vinorelbine and capecitabine

Primary outcome measure
Toxicity, response and survival.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2002

Completion date
25/11/2005

Reason abandoned (if study stopped)
Poor recruitment

Eligibility

Key inclusion criteria
Metastatic breast cancer following initially histologically proven adenocarcinoma of the breast.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
100

Key exclusion criteria
Exclusions include previous treatment with vinorelbine, docetaxel or capecitabine and presence of other primary cancers.

Date of first enrolment
01/04/2002

Date of final enrolment
25/11/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK)

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