

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/10/2012	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

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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/m² intravenous (IV) 30 min DI + 8q 21 days. Capecitabine 1 g/m² orally, twice daily for 14 in every 21 days.

2. Docetaxel 75 mg/m² 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/m² 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