

A trial investigating the impact of medication review on breast cancer patients in a pharmacy technician led outpatient clinic.

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Study information

Scientific Title

Study objectives

To assess whether the introduction of a pharmacy technician led outpatient clinic for breast cancer patients at Worthing Hospital results in an improved level of patient understanding about their chemotherapy support medication. A pharmacy technician clinic will be implemented, the research study will therefore primarily report any benefits of this clinic.

Please note that as of 16/09/10 this record has been updated to include information missing at the time of registration. All information has been taken from the published results paper listed in the publications section below.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 16/09/10:

1. West Sussex Local Research Ethics Committee approved on the 23rd of November 2004 (ref: 04/Q1911/45)
2. The Sussex NHS Research Consortium approved on the 6th of January 2005 (ref: 0457/WASH/2004)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

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

Randomisation into a research or control arm:

Group A: attend pharmacy outpatient clinic

Group B: usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Level of patient understanding:

The chief investigator (HR) interviewed each consented patient using a standard question set, asking the patient to explain what each of their support medications was for and how they used it. Assessments were recorded as an overall rating of the subject's understanding on a Likert scale from 1=very poor to 5=very good, plus a drug-specific score derived from marks awarded for various pieces of information: drug name (+2); indication (+2); dose frequency (+2); dose duration (+1); dose (+1). Thus the maximum score per drug was 8 and the minimum 0. The average score per drug was also calculated. Assessments were conducted prior to randomisation; the chief investigator was blind during subsequent, post-randomisation assessments.

Secondary outcome measures

Added 16/09/10:

1. The numbers of patients experiencing delays in receiving their chemotherapy
2. The numbers of patients requiring chemotherapy dose reductions
3. Numbers of patients having potential drug interactions between GP prescribed medication and chemotherapy or chemotherapy support medication
4. The number of chemotherapy support medication items supplied per patient
5. The average cost of chemotherapy support medication supplied per patient
6. The numbers and costs of chemotherapy support medication not supplied
7. The average amount of pharmacy time per patient spent resolving medication issues
8. The numbers of patients requiring a prescription intervention at the point of dispensing

Overall study start date

06/01/2005

Completion date

08/03/2006

Eligibility

Key inclusion criteria

1. 140 patients being treated for breast cancer and receiving chemotherapy.
2. 18 years and above

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

140

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

06/01/2005

Date of final enrolment

08/03/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Worthing & Southlands Hospitals NHS Trust

Worthing

United Kingdom

BN11 2DH

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

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SW1A 2NL
+44 (0)20 7307 2622
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Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
Sussex NHS Research Consortium (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/03/2007		Yes	No