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A comparative pharmacokinetic study: 5 Fluorouracil (5FU) provided as patient specific individual doses and as standard doses according to a 'dose banding' principle

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/06/2017	**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
N0436118084

Study information

Scientific Title
A comparative pharmacokinetic study: 5 Fluorouracil (5FU) provided as patient specific individual doses and as standard doses according to a 'dose banding' principle

Study objectives
The main aim of the project is to evaluate the concept of dose-binding chemotherapy drugs as a means of improving pharmacy efficiency and reducing patients waiting times. This study aims to compare the plasma profiles of the drug 5FU in breast cancer patients receiving dose-banded and the usual, individually prepared, doses as part of their normal FEC chemotherapy regimen.

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
Cancer: Breast

Interventions
Randomised controlled trial

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
5FU

Primary outcome measure
The comparative plasma concentration profiles (Cmax, AUC) in patients receiving dose-banded and individually prepared doses of 5 Fluorouracil.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2002

Completion date
01/03/2007

Eligibility

Key inclusion criteria
Women with breast cancer who are receiving adjuvant therapy.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
26

Key exclusion criteria
Patients on reduced doses of FEC chemotherapy, with known liver metastases, who have received chemotherapy for previous malignancies.

Date of first enrolment
01/03/2002

Date of final enrolment
01/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James's University Hospital
Leeds
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK), NHS R&D Support Funding

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