

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 14/06/2017	<b>Condition category</b> 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

### Contact name

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### Contact details

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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  
LS9 7TF

## Sponsor information

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**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