

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

Contact name

Ms V A Walker

Contact details

Department of Medical Oncology
Level 4
Gledhow Wing
St James's University Hospital
Leeds
United Kingdom
LS9 7TF
+44 (0)113 243 3144
r&d@leedsth.nhs.uk

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/03/2007

Eligibility

Key inclusion criteria

Women with breast cancer who are receiving adjuvant therapy.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

United Kingdom

England

Study participating centre

St James's University Hospital

Leeds

United Kingdom

LS9 7TF

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration