ISRCTN15898585 https://doi.org/10.1186/ISRCTN15898585

Pharmacokinetic study of capecitabine after total gastrectomy for stomach adenocarcinoma

Submission date 15/06/2009	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/08/2009	**Overall study status** Stopped	
Last Edited 14/05/2019	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-capecitabine-works-stomach-cancer-stomach-removed

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00871273

Secondary identifying numbers
CAP002

Study information

Scientific Title
A pharmacokinetic study of capecitabine in patients undergoing peri-operative chemotherapy and a total gastrectomy for adenocarcinoma of the stomach

Acronym
CAP002

Study objectives
To establish the pharmacokinetics (PK) of capecitabine in patients who have undergone a total gastrectomy, i.e. the action of drug capecitabine in the body over a period of time, including the processes of absorption, distribution, localisation in tissues, biotransformation and excretion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland Research Ethics Committee, 16/06/2009, ref: 09/H0904/38

Study design
Multicentre non-randomised single-arm open-label study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Gastric adenocarcinoma

Interventions
This is a clinical trial to evaluate the PK of adjuvant capecitabine in patients who have undergone a total gastrectomy. The study will compare the pharmacokinetic profile of capecitabine administered to patients with gastric cancer pre- and post-gastrectomy (using patients as their own controls) and also compare the data accrued with historical data for capecitabine PK. The aim is to ensure equivalent capecitabine exposure following total gastrectomy.

Screening tests will consist of demographic details, complete medical history, physical exam, vital signs, haematology and biochemistry tests. Electrocardiogram (ECG), tumour measurement (computed tomography [CT] abdomen, chest X-ray or CT chest) and a serum or urine pregnancy test (for women of childbearing potential) will also be performed. Haematology and biochemistry will be repeated prior to each study drug administration.

All patients will receive ECX chemotherapy which includes epirubicin 50 mg/m^2 (intravenous [iv] bolus) on day 1, cisplatin 60 mg/m^2 (iv infusion) on day 1 and oral capecitabine chemotherapy at a dose of 625 mg/m^2 administered twice daily at 12 hourly intervals for 21 consecutive days out of a 21-day cycle.

Capecitabine and its metabolites (DFCR, DFUR and 5-FU) plasma levels will be measured during cycles 1 and 4 in all patients, using a validated HPLC-MS method. An optional pharmacogenetic sample will be collected prior to the start of chemotherapy treatment. Treatment will continue for 3 cycles pre-operatively and 3 cycles post-operatively unless there is evidence of disease progression on chemotherapy, unacceptable toxicity or treatment is discontinued at the patient's request.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Capecitabine

Primary outcome measure
To establish the PK of capecitabine in patients who have undergone a total gastrectomy, measured at week 18 +/- 2

Secondary outcome measures
1. To compare the PK profile of capecitabine administered to patients with gastric cancer pre- and post-gastrectomy and to compare this to historical data of capecitabine PK values in patients with other cancer types
2. To ensure equivalent capecitabine exposure when compared to previous studies using patients who have not undergone such surgery

Measured at PK analysis.

Overall study start date
01/08/2009

Completion date
30/11/2013

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Histological confirmation of gastric carcinoma suitable for potentially curative resection
2. Surgery must be planned to involve a total gastrectomy
3. No concurrent mechanical or malabsorptive disorders precluding affective oral administration of the drug (excluding early satiety related to the presence of the malignancy)
4. Aged greater than or equal to 18 years, either sex
5. World Health Organisation (WHO) performance status of less than or equal to 2
6. Haematological and biochemical indices (these measurements must be performed within one week prior to the patient going on study):
6.1. Haemoglobin (Hb) greater than or equal to 9.0 g/dl
6.2. Neutrophils greater than or equal to 1.5 x 10^9/l
6.3. Platelets (Plts) greater than or equal to 100 x 10^9/l
6.4. Serum bilirubin less than or equal to 1.5 x upper normal limit (ULN)
6.5. Alanine amino-transferase (ALT) and/or aspartate amino-transferase (AST) less than or equal to 2.0 x ULN (if both are measured, both must be less than or equal to 2.0 x ULN)
6.6. Calculated creatinine clearance greater than or equal to 50 ml/min (uncorrected value) or isotope clearance measurement greater than or equal to 50 ml/min
7. Female patients of child-bearing potential must have a negative serum or urine pregnancy test within two weeks prior to enrolment and agree to use appropriate medically approved contraception for four weeks prior to entering the trial, during the trial, and for six months afterwards
8. Male patients must agree to use appropriate medically approved contraception during the trial and for six months afterwards
9. Written, informed consent provided
10. Ability of the patient to co-operate with treatment and follow up must be ensured
11. Patients receiving oral anti-coagulation prior to entry into the study, must be converted to low molecular weight heparin in light of the interaction between capecitabine and warfarin

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Patients with gastric lymphoma or other histological diagnosis
2. Any evidence of malignant ascites, peritoneal or liver metastasis, spread to other distant abdominal or extra-abdominal organs
3. History of confirmed ischaemic heart disease, concurrent congestive heart failure or prior history of class III/IV cardiac disease
4. Concurrent mechanical or malabsorptive disorders precluding effective oral administration of the drug

5. Use of other concomitant chemotherapy
6. Pregnancy or lactation
7. Patients known to be serologically positive for hepatitis B, hepatitis C or human immunodeficiency virus (HIV)
8. Patients who are high medical risks because of non-malignant systemic disease including active uncontrolled infection
9. Any other serious medical or psychological condition precluding adjuvant treatment
10. Patients with any other condition that in the Investigator's opinion would not make the patient a good candidate for the clinical trial

Date of first enrolment
01/11/2009

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oncology Centre
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
R&D Department, Box 146
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Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Industry

Funder Name
Roche (UK)

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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?
HRA research summary			28/06/2023	No	No