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Pharmacokinetic study of adjuvant capecitabine after resection of pancreatic adenocarcinoma

Submission date 15/06/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/08/2009	**Overall study status** Completed	
Last Edited 20/03/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-study-looking-capecitabine-after-surgery-for-cancer-pancreas-cap-001

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00854477

Protocol serial number
CAP001

Study information

Scientific Title

A pharmacokinetic study of adjuvant capecitabine in patients who have undergone proximal pancreatico-duodenectomy for resection of pancreatic adenocarcinoma

Acronym
CAP001

Study objectives
1. To establish the pharmacokinetics (PK) of capecitabine in patients who have undergone proximal pancreatico-duodenectomy, 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
2. To ensure equivalent capecitabine exposure when compared to previous studies using patients who have not undergone such surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
London, Northwick Park Hospital REC Committee, 07/08/2009, REC ref: 09/H0718/27

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pancreatic adenocarcinoma

Interventions
This is a clinical trial to evaluate the PK of adjuvant capecitabine in patients who have undergone proximal pancreatico-duodenectomy. The study also aims to establish the toxicity profile of capecitabine in these patients, to identify any dose limiting toxicities (DLT), and to ensure equivalent capecitabine exposure when compared to previous studies using patients who have not undergone such surgery. Screening tests will consist of demographic details, complete medical history, physical exam, vital signs, tumour serum markers, haematology and biochemistry tests. There will also be an electrocardiogram (ECG), faecal elastase measurement and a serum or urine pregnancy test (for women of childbearing potential). Haematology and biochemistry (including CA19.9) will be repeated prior to each study drug administration.

All patients will receive 8 cycles of oral capecitabine chemotherapy at a dose of 1250 mg/m^2, administered twice daily at 12-hourly intervals for 14 consecutive days out of a 21-day cycle. Total proposed duration of therapy is 24 weeks, assuming patients commence all cycles without delay. Capecitabine and its metabolites (DFCR, DFUR and 5-FU) plasma levels will be measured during cycles 1 and 3 in all patients.

An optional pharmacogenetic blood sample will be collected prior to the start of chemotherapy treatment. Treatment should continue for 8 cycles unless there is evidence of disease progression, or unacceptable toxicity.

Intervention Type
Drug

Phase
Phase I

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

Primary outcome(s)
To establish the PK of capecitabine in patients who have undergone proximal pancreaticoduodenectomy, measured at week 7.

Key secondary outcome(s)
1. To establish the toxicity profile of capecitabine in these patients and to identify any dose limiting toxicities (DLT), measured at week 24
2. To ensure equivalent capecitabine exposure when compared to previous studies using patients who have not undergone such surgery, measured at PK analysis

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. Complete macroscopic resection for pathologically proven ductal adenocarcinoma (or poorly differentiated/undifferentiated carcinoma) of the pancreas (R0 or R1 resection)
2. Surgery must have included a proximal pancreatico-duodenectomy
3. Histological confirmation of the primary diagnosis and examination of all resection margins
4. At least 4 weeks since surgery, fully recovered from the operation and all surgical wounds fully healed
5. Aged greater than or equal to 18 years, either sex
6. World Health Organisation (WHO) performance status of less than or equal to 2
7. Haematological and biochemical indices (these measurements must be performed within one week prior to the patient being registered on the study):
7.1. Haemoglobin (Hb) greater than or equal to 9.0 g/dl (patients may be transfused to this level, however, Hb must be above 9.0 g/dl before registration)
7.2. Neutrophils greater than or equal to 1.5 x 10^9/l
7.3. Platelets (Plts) greater than or equal to 100 x 10^9/l
7.4. Serum bilirubin less than or equal to 1.5 x upper normal limit (ULN)
7.5. 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)
7.6. 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
8. 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
9. Male patients must agree to use appropriate medically approved contraception during the trial and for six months afterwards
10. Written, informed consent provided
11. Ability of the patient to co-operate with treatment and follow up must be ensured
12. 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients with pancreatic lymphoma or other histological diagnosis
2. Macroscopically remaining tumour (R2 resection)
3. Evidence of malignant ascites, peritoneal or liver metastasis, or spread to other distant abdominal or extra-abdominal organs
4. History of confirmed ischaemic heart disease, concurrent congestive heart failure or prior history of class III/IV cardiac disease
5. Concurrent mechanical or malabsorptive disorders precluding affective oral administration of the drug (excluding malabsorption related directly to proximal pancreatic-duodenectomy)
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 which 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
06/12/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oncology Centre
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

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., Roche Holdings, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No