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A randomised placebo-controlled study evaluating the role of pyridoxine in controlling capecitabine-induced hand-foot syndrome

Submission date 14/12/2005	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/02/2006	**Overall study status** Stopped	
Last Edited 19/03/2020	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-to-see-if-pyridoxine-can-help-relieve-hand-foot-syndrome-caused-by-capecitabine

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-000325-29

IRAS number

ClinicalTrials.gov number
NCT00559858

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised placebo-controlled study evaluating the role of pyridoxine in controlling capecitabine-induced hand-foot syndrome

Acronym
CAPP-IT

Study objectives
Can pyridoxine reduce the need to modify the administration (by delaying or reducing the dose) of capecitabine chemotherapy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northampton and Rutland Research Ethics Committee 2, reference number 04 /Q2502/24, approved 10 June 2004

Study design
Interventional, randomised, placebo-controlled

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Hand-foot syndrome in patients with advanced colorectal or breast cancer

Interventions

1. Double-blind randomised controlled trial of pyridoxine versus placebo
2. Sweat test
3. Additional 20 ml bloods
4. Urine (20 ml) at up to three clinic visits
5. Quality of life questionnaire
6. Hand-Foot Syndrome (HFS) assessment form

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
To determine whether pyridoxine can reduce the need for chemotherapy dose modifications (dose delay and dose reductions).

Secondary outcome measures
1. Incidence of capecitabine-induced HFS
2. Overall toxicity
3. Quality of life
4. Response to chemotherapy
5. Progression-free survival
6. Measurement of biomarkers which might predict the occurrence of HFS

Overall study start date
01/06/2004

Completion date
31/05/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with advanced colorectal or breast carcinoma receiving single agent capecitabine chemotherapy
2. No other concomitant chemotherapy or immunotherapy
3. Life expectancy more than 12 weeks
4. Performance status zero, one or two (Eastern Cooperative Oncology Group [ECOG] performance scale)
5. Aged over 18 years
6. Laboratory parameters:
a. Haemoglobin B more than 10 g/dl

b. Platelets more than 100,000 mm^3
c. White Cell Count (WCC) more than 3.0 x 10^9/l
d. Absolute Neutrophil Count (ANC) more than 1.5 x 10^9/l
e. Bilirubin less than 1.3 times Upper Limit of Normal (ULN)
f. Alkaline phosphatase less than five times ULN
g. Transaminases less than five times ULN
h. Creatinine less than 1.5 times ULN
7. Written informed consent provided by the patient
8. Radiotherapy during the study period is allowed
9. Women of child-bearing potential must have a negative pregnancy test prior to study entry and be using adequate contraception, which must be continued for three months after the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
270, 135 in the control group

Key exclusion criteria
1. Any concomintant chemotherapy or immunotherapy
2. Any previous investigational agent within the last six weeks
3. Any other serious or uncontrolled illness, which in the opinion of the investigator, makes it undesirable for the patient to enter the trial
4. Any medical or psychiatric condition which would influence the ability to provide informed consent

Date of first enrolment
01/06/2004

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Oncology Centre
Cambridge
United Kingdom
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrookes Hospital
Trust Research and Development Department
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Industry

Funder Name
Roche Pharmaceuticals

Funder Name
Addenbrookes Oncology Centre R&D Fund

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?
Plain English results				No	Yes
Results article	results	01/08/2012	31/01/2019	Yes	No