

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/02/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

Dr Pippa Corrie

Contact details

Oncology Centre
Box 193
Addenbrookes Hospital
Hills road
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 274376
pippa.corrie@addenbrookes.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2004-000325-29

ClinicalTrials.gov (NCT)

NCT00559858

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 mm³
 - c. White Cell Count (WCC) more than $3.0 \times 10^9/l$
 - d. Absolute Neutrophil Count (ANC) more than $1.5 \times 10^9/l$
 - 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Any concomitant 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**

United Kingdom

England

Study participating centre

Oncology Centre

Cambridge

United Kingdom

CB2 2QQ

Sponsor information**Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

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

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?
Results article	results	01/08/2012	31/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes