

PACT (Patient Preferences in Adjuvant Colorectal Cancer Therapy): a randomised crossover clinical trial comparing bolus fluorouracil/leucovorin to capecitabine as treatment for moderate to high risk resected colorectal cancer

Submission date 09/03/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 19/04/2005	Overall study status Completed	
Last Edited 26/10/2018	Condition category Cancer	

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-different-ways-having-chemotherapy-after-surgery-for-bowel-cancer-pact>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MO05/6844

Study information

Scientific Title

PACT (Patient Preferences in Adjuvant Colorectal Cancer Therapy): a randomised crossover clinical trial comparing bolus fluorouracil/leucovorin to capecitabine as treatment for moderate to high risk resected colorectal cancer

Acronym

PACT

Study objectives

Adjuvant drug therapy reduces the risk of recurrence and death after resection of colorectal cancer, and is recommended routinely for all fit patients if at moderate-to-high risk of recurrence. Standard therapy is intravenous 5-fluorouracil and leucovorin (FU/LV). Large randomised controlled trials have already established that: a. 6 months' FU/LV is as effective as longer courses, and b. Once-weekly treatment is as effective as, but less toxic than, 5 consecutive days repeated monthly.

A recent trial (X-ACT) showed with high statistical confidence that oral capecitabine is as effective as intravenous FU/LV, so it presents an attractive alternative option. Capecitabine gave an acceptable toxicity profile in comparison with the FU/LV regimen used in that trial, although that was the 5-days monthly regimen which is known to be more toxic than weekly treatment.

Capecitabine is likely to become available for adjuvant use during 2005. Its equivalence of efficacy is not in doubt, but in order to advise patients we will require direct comparative data for the toxicity and acceptability to patients of capecitabine in comparison with the current commonly-used UK standard of weekly bolus FU/LV. The PACT trial will provide that comparison.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised active controlled crossover group trial

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

Colorectal cancer

Interventions

A randomised crossover clinical trial comparing bolus fluorouracil/leucovorin to capecitabine

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-fluorouracil/leucovorin, capecitabine

Primary outcome measure

Patient preference for one of two regimens 12 weeks after randomisation, when the patient will have experienced both regimens

Secondary outcome measures

1. Patient preference at 12 weeks, after experiencing both regimens, according to treatment sequence
2. Toxicity - maximum NCIC grade toxicity experienced within first cycle of regimen
3. Quality of Life (QoL) - assessed at baseline, 6, 12 and 24 weeks post-randomisation. Assessed using EORTC QLQ-C30.
4. Dose intensity (DI) - delivered DI as a percentage of planned DI
5. Safety - comparison of rates of SAEs and SUSARS between the two regimens

Overall study start date

01/04/2005

Completion date

31/03/2006

Eligibility**Key inclusion criteria**

Patients aged 18 years or above with Dukes stage C or B colonic or rectal carcinoma, primary fully macroscopically resected (R0 or R1 resection), with no radiological or clinical evidence of metastatic disease (for Dukes B patients there must be a clinical indication for adjuvant

chemotherapy, based on histological risk factors and patient factors) OR full resection of recurrent/metastatic colorectal cancer, if the patient was not previously treated with adjuvant chemotherapy.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

74

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2005

Date of final enrolment

31/03/2006

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Academic Unit of Oncology & Haematology

Leeds

United Kingdom

LS16 6QB

Sponsor information**Organisation**

University of Leeds (UK)

Sponsor details

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Worsley Building
Clarendon Way
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United Kingdom
LS2 9NL

Sponsor type

Industry

ROR

<https://ror.org/024mrxd33>

Funder(s)**Funder type**

Industry

Funder Name

Roche Products Ltd (UK) (Unconditional pharmaceutical study grant)

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	10/07/2008		Yes	No