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A phase I/IIa study combining curcumin (Curcumin C3 Complex, Sabinsa) with standard care FOLFOX chemotherapy in patients with inoperable colorectal cancer

Submission date
28/10/2011

Recruitment status
No longer recruiting

Registration date
28/10/2011

Overall study status
Completed

Last Edited
04/09/2019

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/trial-looking-at-curcumin-and-folfox-for-advanced-bowel-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-002289-19

ClinicalTrials.gov (NCT)
NCT01490996

Protocol serial number
10672

Study information

Scientific Title
A phase I/IIa study combining curcumin (Curcumin C3 Complex, Sabinsa) with standard care FOLFOX chemotherapy in patients with inoperable colorectal cancer

Acronym
FOLFOX plus curcumin in patients with inoperable colorectal cancer

Study objectives
Phase I/IIa study administering daily oral C3-complex curcumin to patients receiving standard care folinic acid (FOL) fluorouracil (F) and Oxalipatin (OX) (FOLFOX) chemotherapy.

Phase I is a dose-escalation response study to establish a maximum tolerated dose. Phase IIa is a two-armed control study comparing FOLFOX+curcumin with FOLFOX alone. The second phase is randomised. Between 42 and 51 patients will be recruited depending on dose-limiting toxicities observed in phase I. Treatment will last for up to 12 cycles (approx 6 months of chemotherapy). Recruitment is anticipated to take 3 years. Follow-up will include routine CT scans to monitor progression, and ultimately survival times. Median survival approx 18 months and <5% 5 year survival, therefore potential running time 7 years in the event of extremely favourable treatment response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands (Derby 1) regional ethics committee , 04/08/2011, ref: 11/EM/0263

Study design
Randomised; Interventional and Observational; Design type: Treatment, Case-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Colorectal Cancer; Disease: Colon

Interventions
This study is the first to combine daily oral curcumin with standard care FOLFOX-based (5-fluorouracil, folinic acid and oxaliplatin) chemotherapy in colorectal cancer patients with inoperable liver metastases: the CUFOX trial. CUFOX comprises a Phase 1 dose-escalation study (3+3+3 design) to determine an acceptable target dose of curcumin with which to safely proceed to a Phase IIa open-labelled randomised controlled trial. Thirty three participants with histological or cytological confirmation of inoperable colorectal cancer will then be randomised

to oxaliplatin-based chemotherapy with the addition of daily oral curcumin at the target dose determined in Phase I, or to standard care oxaliplatin-based chemotherapy alone (recruiting at a ratio of 2:1).

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Folinic acid, fluorouracil, oxaliplatin, curcumin

Primary outcome(s)
Safety; Timepoint(s): Real-time adverse event reporting using Common Terminology Criteria for Adverse Events (CTC-AE), diaries and direct consultation.

Key secondary outcome(s))
1. Biomarker Discovery; Timepoint(s): Samples taken during treatment phase 1-2years. Analysis 3-4 years.
2. Efficacy; Timepoint(s): Measured by response (RECIST) and survival
3. Measurement of systemic curcumin; Timepoint(s): During treatment phase
4. Neurotoxic side-effects; Timepoint(s): 2 weekly neurotoxicity questionnaires
5. Tolerability/Establishing Target Dose; Timepoint(s): Completion dose escalation phase of 3 consecutive patients without dose-limiting toxicitiy 2 cycles

Completion date
09/01/2015

Eligibility

Key inclusion criteria
1. Histological or cytological diagnosis of metastatic colorectal cancer
2. Measurable disease by Response Evaluation Criteria in Solid Tumours version 1.1 (RECIST 1.1)
3. Adequate haematological, hepatic and renal function
4. Age more than or equal to 18 years
5. Eastern Cooperative Oncology Group (ECOG) Performance status 0 or 1
6. Patients must have recovered from effects of any recent major surgery
7. Willing to use contraception if applicable
8. Informed consent
9. Life expectancy estimated to be more than 12 weeks; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
28

Key exclusion criteria
1.Contraindications to FOLFOX chemotherapy: Peripheral neuropathy National Cancer Institute Common Toxicity Criteria (NCI CTC) >1, Liver failure, uncontrolled coronary heart disease, myocardial infarction within the previous 6 months.
2. Unwilling or unable to comply with the study protocol
3. Patients who are pregnant or lactating or contemplating pregnancy. Patients or their partners who become pregnant during the study will be referred to the appropriate experts.
4. Undergone chemotherapy (other than adjuvant for CRC) or participating in another drug study.
5. Previous cancer <5 years (other than colorectal, basal cell carcinoma, in-situ cervical cancer)
6. Major surgery within 4 weeks of starting the study
7. Co-existing active infection or serious concurrent medical condition
8. Significant cardiovascular disease
9. Bone metastases
10. Known brain or leptomeningeal metastases
11. Surgery or hospital admissions for symptomatic intra-abdominal adhesions
12. Active endoscopically proven peptic ulcer disease or colitis

Date of first enrolment
09/01/2012

Date of final enrolment
09/01/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Leicester (UK)

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Bowel Disease Research Foundation of ACPGBI (UK)

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Hope Against Cancer (UK)

Funder Name
Royal College of Surgeons of England (UK)

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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?
Results article	results	01/07/2019	04/09/2019	Yes	No
Protocol article	protocol	24/03/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes