

Colonic curcumin tissue levels in patients awaiting colorectal endoscopy or patients with colorectal cancer awaiting resection

Submission date 29/05/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/08/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/10/2018	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-curcumin-to-help-prevent-bowel-cancer>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00973869

Protocol serial number

CTAAC protocol 230508, Version 3

Study information

Scientific Title

A pilot study of the administration of curcumin to determine colonic curcumin tissue levels in patients awaiting colorectal endoscopy or patients with colorectal cancer awaiting resection

Acronym

CTAAC Pilot of curcumin

Study objectives

To assess colorectal tissue levels of curcumin in individuals who have taken 1.8 g of curcumin daily for 14 days. Patients are either from the National Colorectal Cancer Screening Programme or from those waiting resection of colorectal cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES, Northern & Yorkshire Research Ethics Committee, 29/11/2007, ref: 07/MRE03/31

Study design

Single arm non-randomised pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

1. Endoscopy but only as part of routine screening under the National Colorectal Cancer Screening Programme
2. Resection of colorectal cancer by surgery

All patients will receive curcumin 1.8 g daily as tablets for 14 days prior to endoscopy. Patients will be contacted once, 7 days after completing curcumin, to ensure that no late effects have occurred.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Curcumin

Primary outcome(s)

From 30 eligible patients who are compliant in taking all doses have tissue measurement of curcumin greater than or equal to 5 nMol/g tissue, assessed approximately two months after completion of the trial when the colon biopsies will be assayed in the laboratories for curcumin levels. The exact timing of assay will vary depending on the number of samples which will be batched together for assessment.

Key secondary outcome(s)

To assess the practicality, acceptability and safety of individuals taking 5 capsules of curcumin (2.25 g total daily dose of curcuminoids, 1.8 g curcumin) daily for 14 days, assessed at 3 weeks from entry to the study.

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

1. Found to have faecal occult blood (FOB) as part of National Colorectal Cancer Screening Programme or those awaiting resection of known colorectal cancer
2. Over 18 years of age, either sex
3. Using contraception

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. History in past year of discrete gastric or duodenal ulcer of size greater than 5 mm
2. Inability to return for follow up tests
3. Significant medical or psychiatric problems (including renal, hepatic or haematological dysfunction)
4. Use of any investigational agent within last 3 months
5. History of pelvic radiation
6. Women of child bearing age unless they agree to provide written confirmation that they are using adequate contraception

Date of first enrolment

01/07/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Leicester Royal Infirmary

Leicester

United Kingdom

LE1 5WW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) grant (ref: 07/034)

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

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	01/02/2013		Yes	No
Plain English results				No	Yes