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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2009	**Overall study status** Completed	
Last Edited 26/10/2018	**Condition category** Cancer	

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
Prof William Steward

Contact details
CSMM
2nd Floor
Osborne Building
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW
+44 (0)116 258 7597
wps1@le.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00973869

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/07/2009

Completion date
31/12/2011

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
30

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
England

United Kingdom

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

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
c/o Professor David Rowbotham
Director of Research and Development

Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4QF
+44 (0)116 258 4199
djr8@le.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/02/2013		Yes	No