ISRCTN93128659 https://doi.org/10.1186/ISRCTN93128659

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

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| **Submission date**<br>29/05/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/08/2009 | **Overall study status**<br>Completed | |
| **Last Edited**<br>26/10/2018 | **Condition category**<br>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

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## 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
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## Sponsor information

### Organisation
University Hospitals of Leicester NHS Trust (UK)

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

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### 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 |