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A multi-centre double blind randomised controlled trial of aspirin and/or folate supplementation for the prevention of recurrent colorectal adenomas

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 18/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ukCAP

Study information

Scientific Title
A multi-centre double blind randomised controlled trial of aspirin and/or folate supplementation for the prevention of recurrent colorectal adenoma

Study objectives
To determine whether aspirin (300 mg/day) and/or folic acid (0.5 mg/day) could be used to prevent further colorectal adenomas in the high risk group of patients with previous colorectal adenomas removed by colonoscopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. LREC approval (Nottingham): gained on 19/11/98 (ref: EC98/203)
2. MREC approval (Trent): gained on 02/12/03 (ref: 98/4/055)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Recurrent colorectal adenomas

Interventions
Arm A: aspirin and folate
Arm B: aspirin and placebo folate
Arm C: placebo aspirin and folate
Arm D: placebo aspirin and placebo folate

Aspirin 300 mg E.C/day; folate 500 ug/day

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Aspirin, folate

Primary outcome measure
Percentage of patients who developed one or more recurrent colorectal adenomas or cancers

Secondary outcome measures
1. Number of recurrent adenomas detected during follow-up
2. Percentage of patients who developed advanced colorectal neoplasia during follow-up

Overall study start date
01/12/1997

Completion date
01/07/2005

Eligibility

Key inclusion criteria
Eligible patients who have had:
1. Removal of adenomas greater than 0.5 cm after fixation or adenomas greater than 0.7 cm at the time of removal, within the last six months
2. A previous history of removal of such adenomas and have had adenoma of any size removed in the six months prior to recruitment These adenomas will be histologically confirmed and removed by either colonoscopy, flexi-sigmoidoscopy or via Transanal Endoscopic Microsurgery (TEMS) procedure

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1,000

Key exclusion criteria
1. Over 75 years at time of recruitment
2. Serious medical conditions likely to preclude successful completion of the trial
3. Existing use of prescribed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) including aspirin
4. Known aspirin intolerance or sensitivity
5. Active bleeding disorders or upper Gastrointestinal (GI) ulceration, including use of

anticoagulants
6. Previous resection of the large bowel

Date of first enrolment
01/12/1997

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Denmark

England

United Kingdom

Study participating centre
School of Community Health Sciences
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR

https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

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	01/01/2008		Yes	No