ISRCTN22669537 https://doi.org/10.1186/ISRCTN22669537

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

Protocol serial number
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

Study type(s)
Prevention

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(s)
Percentage of patients who developed one or more recurrent colorectal adenomas or cancers

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Denmark

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

Sponsor information

Organisation
Cancer Research UK (CRUK) (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, 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	01/01/2008		Yes	No
Plain English results				No	Yes