

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Richard Logan

Contact details
School of Community Health Sciences
Medical School
University of Nottingham
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 823 0452
Richard.Logan@nottingham.ac.uk

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

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