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Concerted Action Polyp Prevention

Submission date 18/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/09/2005	**Overall study status** Completed	
Last Edited 25/09/2012	**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
1

Study information

Scientific Title

Acronym
CAPP1

Study objectives
Daily use of aspirin and resistant starch will reduce the risk of polyp formation and of subsequent colon cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

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
Familial Adenomatous Polyposis (FAP)

Interventions
Factorial design of:
A. 600 mg Aspirin and 30 g Resistant Starch
B. Placebo Aspirin and 30 g Resistant Starch
C. 600 mg Aspirin and 30 g Placebo Starch
D. Placebo Aspirin and Placebo Starch

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aspirin, resistant starch

Primary outcome measure
1. Age at colectomy
2. Reduction in size of polyps
3. Changes in crypt cell proliferation

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1993

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Known carriers of familial adenomatous polyposis (FAP), either by molecular genetic analysis or by phenotypic features
2. Over 10 years of age with an intact colon

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Already taking Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
2. Partial Resection
3. If over 21 years of age - to take treatment for 1 year only

Date of first enrolment
01/01/1993

Date of final enrolment
31/12/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Institute of Human Genetics
Newcastle upon Tyne
United Kingdom
NE1 3BZ

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Trust (UK)

Sponsor details
R and D Department
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
European Union Biomedical and Health Research - Biomed 1 Programme

Funder Name
Bayer Corporation (UK)

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?
Protocol article	protocol	01/07/1995		Yes	No
Results article	results	01/05/2011		Yes	No