ISRCTN83743312 https://doi.org/10.1186/ISRCTN83743312

Concerted Action Polyp Prevention

Submission date
18/08/2005

Recruitment status
No longer recruiting

Registration date
15/09/2005

Overall study status
Completed

Last Edited
25/09/2012

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof John Burn

Contact details
Institute of Human Genetics
Centre for Life
Central Parkway
Newcastle upon Tyne
United Kingdom
NE1 3BZ

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

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(s)
1. Age at colectomy
2. Reduction in size of polyps
3. Changes in crypt cell proliferation

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Trust (UK)

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

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