

Concerted Action Polyp Prevention

Submission date 18/08/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 15/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/09/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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