# Finding the best dose of aspirin to prevent Lynch Syndrome cancers

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
14/10/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/10/2015	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
20/08/2025	Cancer			

## Plain English summary of protocol

http://www.cancerresearchuk.org/about-cancer/trials/a-trial-looking-at-different-doses-of-aspirin-to-prevent-cancer-in-people-with-lynch-syndrome-capp3

## Contact information

## Type(s)

Public

#### Contact name

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## Type(s)

Scientific

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## Additional identifiers

Clinical Trials Information System (CTIS)

2014-000411-14

Integrated Research Application System (IRAS)

141927

ClinicalTrials.gov (NCT)

NCT02497820

Protocol serial number

17122

# Study information

#### Scientific Title

A randomised double blind dose non-inferiority trial of a daily dose of 600 mg versus 300 mg versus 100 mg of enteric-coated aspirin as a cancer preventive in carriers of a germline pathological mismatch repair gene defect, Lynch Syndrome. Project 3 in the Cancer Prevention Programme (CaPP3).

## Acronym

CaPP3

## **Study objectives**

The aim of this study is to find the most effective dose of aspirin for people with a mismatch repair gene defect, the underlying cause of Lynch syndrome.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 15/05/2014, NRES Committee North East - Newcastle & North Tyneside 2 (Health Research Authority Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; no telephone number provided; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 14/NE/0103

## Study design

Randomized; Interventional; Design type: Screening, Treatment

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Lynch syndrome

#### **Interventions**

Participants are asked to take three tablets each day for 2 years. One tablet will be a placebo, and at least one of the tablets will contain enteric-coated aspirin at a dose of either 100, 300 or 600 mg. After 2 years on the blinded dose, participants will be given 100mg open-label enteric-coated aspirin until the last recruit reaches their fifth anniversary. Drug packs will be delivered directly to the patient to save them from travelling to collect the drug. They will be routinely followed up by an initial phone call at 3 months and then 6-monthly thereafter for the blinded phase. In the open-label phase, only yearly follow-ups will be required. The aim is to balance adequate safety follow-up whilst remaining mindful that patients are not "sick", so minimising travelling to hospital and being in a clinical environment unnecessarily.

#### Intervention Type

Drug

#### Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Aspirin

## Primary outcome(s)

The frequency of Lynch Syndrome Cancers is determined throughout the study and during 10 years following the end of the study.

## Key secondary outcome(s))

Not provided at time of registration

## Completion date

15/07/2024

## **Eligibility**

## Key inclusion criteria

- 1. Aged 18 years or over
- 2. Confirmed germline pathological variant in one of the mismatch repair genes: MSH2, MLH1, PMS2 or MSH6 or a 3' EPCAM deletion associated with MSH2 silencing or be a carriers of a constitutional epimutation manifesting a classic Lynch syndrome phenotype
- 3. Able to swallow tablets
- 4. Willing to complete the CaPP3 consent process as described in the patient information sheet

## Participant type(s)

Patient

## Healthy volunteers allowed

## Age group

Adult

## Lower age limit

18 years

#### Sex

Αll

#### Total final enrolment

1567

#### Key exclusion criteria

- 1. Regular use of a non-steroidal anti-inflammatory agent (except aspirin\*) on a prescription and /or long-term basis. Regular is defined as >3 doses per week
- 2. Regular use of aspirin (>3 doses per week or on a prescription basis) that cannot be replaced with any one of the randomised arms of the study followed by 100 mg dose
- 3. Known aspirin intolerance or hypersensitivity, including aspirin-sensitive asthma
- 4. Existing clinically significant liver impairment
- 5. Existing renal failure
- 6. Confirmed active peptic ulcer disease within the previous three months
- 7. Known bleeding diathesis or concomitant anticoagulant therapy
- 8. Inability to comply with study procedures and agents
- 9. Women reporting that they are pregnant or actively planning to achieve a pregnancy within the next two years
- 10. Women who are breastfeeding
- 11. Any significant medical illness that would interfere with study participation. (If hypertension is discovered, the participant should be advised to have this treated before commencing trial medication)
- 12. Participation in the previous CAPP2 study will not exclude patients from this study, apart from the small number recruited less than 10 years previously
- \*Previous use of aspirin for medicinal purposes does not exclude enrollment but duration and quantity need to be documented in detail.

#### Date of first enrolment

01/10/2014

#### Date of final enrolment

31/03/2019

## Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre Institute of Human Genetics

International Centre For Life Central Parkway Newcastle Upon Tyne United Kingdom NE1 3BZ

# Sponsor information

## Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

### **ROR**

https://ror.org/05p40t847

# Funder(s)

## Funder type

Charity

#### **Funder Name**

Cancer Research 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** 

#### **Funder Name**

Bayer Pharmaceuticals Plc

# **Results and Publications**

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results			20/08/2025	No	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes