Finding the best dose of aspirin to prevent Lynch Syndrome cancers

Submission date	Recruitment status	Prospectively registered
Decision date		Protocol Statistical analysis plan
14/10/2015	Completed	Results
Last Edited	Condition category	 Individual participant data [X] Record updated in last year
,	Concer	

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

Study website

http://www.capp3.org/

Contact information

Type(s)

Public

Contact name

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Contact details

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Type(s)

Scientific

Contact name Dr . Study Team

Contact details

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Additional identifiers

EudraCT/CTIS number 2014-000411-14

IRAS number 141927

ClinicalTrials.gov number NCT02497820

Secondary identifying numbers 17122

Study information

Scientific Title

A randomised double blind dose non-inferiority trial of a daily dose of 600mg versus 300mg versus 100mg 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

Randomised; Interventional; Design type: Screening, Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

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

Lynch syndrome

Interventions

Participants are asked to take three tablets each day for two years. One tablet will be a placebo, and at least one of the tablets will contain enteric coated aspirin at a dose of either 100mg, 300mg or 600mg. 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 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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date 01/10/2014

Completion date

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

Age group Adult

Lower age limit

18 Years

Sex Both

Target number of participants

Planned Sample Size: 3000; UK Sample Size: 750; Description: As the NHS in the UK are not permitted to sponsor studies overseas, we are encouraging colleagues in other countries to replicate our design exactly which will allow us to pool data. If this is successful we estimate the UK contribution will be 750-1500, with most of the rest coming from EU countries and Australia. All overseas investigatorsrunning parallel studies are responsible for satisfying all their own countries' ethical and regulatory processes.

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 100mg 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 England

United Kingdom

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

Sponsor details Institute of Genetic Medicine International Centre for Life Central Parkway Newcastle upon Tyne England United Kingdom NE1 3BZ

Sponsor type Hospital/treatment centre ROR https://ror.org/05p40t847

Funder(s)

Funder type Charity

Funder Name Cancer Research 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

Funder Name Bayer Pharmaceuticals Plc.

Results and Publications

Publication and dissemination plan Planned publication in a peer-reviewed journal

Intention to publish date 31/08/2025

Individual participant data (IPD) sharing plan Not provided at time of registration

IPD sharing plan summary Not provided at time of registration

Study outputs Output type HRA research summary

Details Date created

Date added 28/06/2023

ed Peer reviewed?

d? Patie No

Patient-facing? No