ISRCTN16261285 https://doi.org/10.1186/ISRCTN16261285

Finding the best dose of aspirin to prevent Lynch Syndrome cancers

Submission date	Recruitment status	[_] Prospectively registered
14/10/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/10/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2024	Cancer	[X] Record updated in last year

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

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Scientific

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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

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

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
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
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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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No