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Aspirin after hospitalisation with pneumonia to prevent heart attacks and stroke

Submission date
20/09/2022

Recruitment status
Recruiting

Registration date
03/11/2022

Overall study status
Ongoing

Last Edited
24/10/2025

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pneumonia is an inflammation of one or both lungs, usually caused by infection. Most people recover completely but some have complications. Two of the most significant complications are heart attack and stroke. Around 5 in 100 patients who are admitted to hospital with pneumonia have a heart attack or stroke within three months. These events are thought to occur because the infection affects blood vessels and causes clots, reducing the blood reaching the heart or brain.
Aspirin has been used for decades to reduce the chance of having a heart attack or stroke in patients at high risk of either event. It works quickly with limited side effects in the vast majority of patients. Some studies have shown that patients who develop pneumonia and take aspirin have a lower chance of these events.
The ASPECT trial aims to test whether aspirin reduces the risk of a heart attack or stroke in patients who are admitted to hospital with pneumonia. Those who agree to take part will be split into two groups. One group will be asked to take a course of low dose aspirin for 3 months, the other group will not. In all other respects, both groups will have the same treatment.

Who can participate?
Adults aged 50 years and over admitted to hospital with pneumonia will be invited to take part.

What does the study involve?
Those who agree will be split into two groups. One group will be asked to take a course of low dose aspirin each day for 3 months. The other group will not.
We will look at whether participants have had a heart attack or stroke, or any other serious events 3 months after joining the study. We will do this by reviewing the ‘usual care’ health records of participants held by NHS hospitals. This means that participants will not have to do anything. The first 2,000 participants will be asked to complete a questionnaire at 3 months. The questionnaire will ask about side effects and whether the aspirin was taken as prescribed.

What are the possible benefits and risks of participating?
Benefits:
There is a possibility that participants who receive aspirin will have a lower chance of suffering from a stroke or heart attack after pneumonia infection, but we cannot be certain, and this is

what the study will help us find out.
Risks:
Aspirin is a very well profiled drug that is available over the counter and tolerated in much higher doses than the study is giving.
The possible risks of taking part in the study are the side effects from aspirin (commonly; indigestion and increased bleeding), but the dosage in this study is very low, so the chances of side effects are also very low.

There is no concomitant or rescue medication mandated in the Protocol. Treating clinicians may prescribe gastroprotection in those patients randomised to aspirin who are felt to be at the greatest risk of bleeding, but these decisions will be at the discretion of the treating clinician.

Patients already taking an antiplatelet medication will be excluded on the grounds of increased bleeding risk from the addition of aspirin. Patients taking other anti-thrombotic medication, like anti-coagulants, may still be eligible for this trial, but risk of bleeding would be assessed by the treating clinician.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2022 to February 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (HTA) (UK).

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
2022-001856-40

Integrated Research Application System (IRAS)
1005090

Central Portfolio Management System (CPMS)
54032

Protocol serial number
5019

Study information

Scientific Title
Aspirin after hospitalisation with Pneumonia to prevent cardiovascular Events randomised Controlled Trial (ASPECT)

Acronym
ASPECT

Study objectives
Primary objective:
To evaluate the effectiveness of aspirin versus usual standard care in preventing major adverse cardiovascular events (MACE) in patients >= 50 years admitted to hospital with community-acquired pneumonia.

Secondary outcomes will be defined from routine data at 90 days post randomisation:
1. All-cause mortality;
2. Cardiovascular mortality;
3. Bleeding events causing hospitalisation;
4. Hospital length of stay

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/11/2022, Wales Research Ethics Committee 1 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2920785738; Wales.REC1@wales.nhs.uk), ref: 22/WA/0271

Study design
Interventional randomized parallel group controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pneumonia - lung infection

Interventions
Patients will be randomised 1:1 to either receive aspirin or continue with standard care (no aspirin). Participants course of aspirin:
a. 2 tablets of 75mg to be taken daily for 7 days, then;
b. 1 tablet of 75mg to be taken daily for 84 days

The tablets will be dispensed by their treating team whilst they are in hospital. All aspirin will be taken orally. The patient will be discharged with the remaining aspirin to take themselves when they are out of hospital.
Randomisation will either be carried out on a bespoke database or will be SealedEnvolope.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
Current primary outcome measure as of 24/10/2025:
The hierarchical composite of time to cardiovascular mortality, non-cardiovascular mortality, non-fatal MI/stroke, PE/DVT and TIA/unstable angina, up to 90 days following randomisation.

The trial will end for a participant after they have completed the course of study medication at 91 days post randomisation and completed the 90-day follow-up questionnaire (if one of the first 2000 participants recruited during phase 1). The end of the trial as a whole will be after all trial participants have completed follow up, all data queries have been resolved, the database locked and the analyses completed.

Previous primary outcome measure:
Any MACE defined using validated International classification of diseases 10 (ICD-10) codes for specified diagnoses in hospital or cardiovascular death (deaths with any of the specified ICD-10 codes coded as the underlying cause up to 90 days after randomisation.

The trial will end for a participant after they have completed the course of study medication at 91 days post randomisation and completed the 90-day follow-up questionnaire (if one of the first 2000 participants recruited during phase 1). The end of the trial as a whole will be after all trial participants have completed follow up, all data queries have been resolved, the database locked and the analyses completed.

Key secondary outcome(s))
Current secondary outcome measures as of 24/10/2025:
MACE*, all-cause mortality, cardiovascular mortality and major bleeding events up to 90 days following randomisation. MACE defined using validated International Classification of Diseases 10 (ICD-10) codes for specified diagnoses in hospital or cardiovascular death (deaths with any of the specified ICD-10 codes coded as the underlying cause up to 90 days after randomisation.

Previous secondary outcome measures:
Defined from routine data at 90 days post randomisation:
1. All-cause mortality
2. Cardiovascular mortality
3. Bleeding events causing hospitalisation
4. Hospital length of stay

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Aged 50 years and over
2. Symptoms and signs of acute lower respiratory tract infection
3. Radiographic changes in keeping with infection on chest radiograph, CT scan or lung ultrasound scan

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

Key exclusion criteria
1. Already taking regular prescribed anti-platelet medication, including aspirin, clopidogrel, cangrelor, selexipag, cilostazol, dipyridamole, prasugrel, ticagrelor, abciximab, eptifibatide, tirofiban, epoprostenol, iloprost
2. A known allergy, previous important adverse reaction, or contraindication to aspirin
3. At high risk of excessive bleeding (e.g. large trauma or haemorrhage or urgent need for major surgery or uncorrectable coagulopathy) in the opinion of the treating physician
4. Hospital acquired pneumonia, defined as related to an inpatient hospital stay within the last 10 days or acquired at least 48 hours after current admission
5. Discharged without a 'Decision to Admit' to hospital by urgent care/emergency department
6. Unlikely to tolerate/adhere to medication regimen
7. Prisoners
8. Known to be pregnant
9. Life expectancy <3 months due to pre-existing condition (e.g. terminal malignancy)
10. Presentation more likely due to acute COVID-19 pneumonitis in the opinion of the treating physician. i.e. newly positive Polymerase Chain Reaction (PCR) or similar antigen test for COVID-19
11. Enrolment onto another study where the burden on the participant will be too high if they are enrolled onto to both. Or, if the enrolment onto both would compromise one or both of the study's objectives. To be decided on a case-by-case basis.

Date of first enrolment
03/11/2022

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
North

Sponsor information

Organisation

North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	23/08/2023	22/08/2024	No	No
Protocol file	version 4.0		24/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes