

# Aspirin after hospitalisation with pneumonia to prevent heart attacks and stroke

<b>Submission date</b> 20/09/2022	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/08/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English Summary

### 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 November 2025

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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Scientific

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**Additional identifiers****EudraCT/CTIS number**

2022-001856-40

**IRAS number**

1005090

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

5019, IRAS 1005090, CPMS 54032

**Study information****Scientific Title**

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

**Acronym**

ASPECT

**Study hypothesis**

Primary objective:

To evaluate the effectiveness of aspirin versus usual standard care in preventing major adverse cardiovascular events (MACE) in patients  $\geq 50$  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**

Old ethics approval format

**Ethics approval(s)**

Approval pending, ref: 22/WA/0271

**Study design**

Interventional randomized parallel group controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**Condition**

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 SealedEnvelope.

**Intervention Type**

Drug

**Phase**

Phase IV

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

Aspirin

**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.

### **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

### **Overall study start date**

22/08/2022

### **Overall study end date**

30/11/2025

## **Eligibility**

### **Participant inclusion criteria**

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

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

50 Years

### **Sex**

Both

### **Target number of participants**

22600

### **Participant 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.

**Recruitment start date**

03/11/2022

**Recruitment end date**

31/12/2024

## Locations

**Countries of recruitment**

England

United Kingdom

**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

**Sponsor details**

Research and Innovation

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Bristol

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BS10 5NB

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researchsponsor@nbt.nhs

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nbt.nhs.uk/>

**ROR**

<https://ror.org/036x6gt55>

## Funder(s)

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Peer reviewed scientific journals

Internal report

Conference presentation

Publication on website

Submission to regulatory authorities

Other

Data will be made available for sharing subject to the necessary approvals from NHS Digital. Data sharing will be in line with the University of Bristol, Research data management and open data policy and in agreement with NHS Digital. Any shared data will be available after publication of the main results of the study.

**Intention to publish date**

31/10/2026

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 3.0	23/08/2023	22/08/2024	No	No