ISRCTN17439969 https://doi.org/10.1186/ISRCTN17439969

Point of care testing to inform care for chest infections in older adults in primary care: a randomised feasibility study

Submission date
10/11/2025

Recruitment status
Recruiting

Registration date
05/01/2026

Overall study status
Ongoing

Last Edited
03/03/2026

Condition category
Infections and Infestations

[_] 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
Many people visit their GP with chest infections that feel like the flu. These infections are often caused by viruses, but antibiotics only work against bacteria. Despite this, antibiotics are still often prescribed, especially for older adults, because it can be hard to tell what kind of infection someone has. Taking antibiotics when they're not needed can cause side effects and lead to antibiotic resistance, which makes it harder to treat infections in the future. This study is testing whether using quick tests, called point-of-care tests, during GP appointments can help doctors decide if antibiotics are really needed. The study is a small trial to see if a larger one would be possible in the future.

Who can participate?
You may be able to take part if you are aged 65 or over, have had symptoms of a chest infection (like a cough) for less than 7 days, and also have at least one of the following: shortness of breath, phlegm (sputum), or chest pain. You must also be able to give written consent to take part.

What does the study involve?
If you take part, you'll be randomly placed into one of three groups. Each group will have a different type of quick test done during your GP appointment. One group will have a test for COVID-19 and flu. Another group will have the same test plus a test called FebriDx, which looks for signs of bacterial infection. The third group will have the COVID-19 and flu test plus a test for CRP, a marker of inflammation. Your GP will use the results to help decide whether antibiotics are needed. The study will also ask for your feedback and check how well the process works.

What are the possible benefits and risks of participating?
You may benefit by getting a more accurate diagnosis and avoiding unnecessary antibiotics. This could reduce side effects and help protect antibiotics for the future. There are very few risks, but as with any test, there's a small chance of discomfort or a false result. You'll be fully informed before you decide to take part.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
February 2025 to October 2026

Who is funding the study?
National Institute for Health Research Southampton Biomedical Research Centre (UK)

Who is the main contact?
Jenna Garrod, jhg1u23@soton.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Mark Lown

ORCID ID
https://orcid.org/0000-0001-8309-568X

Contact details
Aldermoor Surgery, Off Aldermoor Cl, Coxford Rd
Southampton
United Kingdom
SO16 5ST
+44 23 8024 1000
m.lown@soton.ac.uk

Type(s)
Public, Scientific

Contact name
Miss Jenna Garrod

Contact details
Aldermoor Surgery, Off Aldermoor Cl, Coxford Rd
Southampton
United Kingdom
SO16 5ST
+44 23 8024 1000
jhg1u23@soton.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
341760

Protocol serial number
93645.A2

Central Portfolio Management System (CPMS)
61503

Study information

Scientific Title
Point of care testing to reduce unnecessary antibiotic use for lower respiratory tract infections in older adults in primary care: a randomised feasibility trial

Acronym
POCT65ABX

Study objectives
Aim:
To explore the feasibility of a trial investigating using, and evaluating the use of, pathogen-detection point-of-care tests to help guide the management of LRTIs in older adults in a primary care setting.
Objectives:
1. To assess the feasibility of conducting a trial investigating the use of lateral flow type point-of-care testing to improve the management of older adults with LRTIs in primary care, including recruitment, randomisation, and data collection.
2. To understand the acceptability of, and barriers and facilitators to using COVID-19 and Influenza A/B lateral flow type tests, with and without biomarker point-of-care tests, to help guide the management of lower respiratory tract infections (LRTI) in older adults in primary care.
3. To estimate the effects of using these tests on use of antimicrobials, in order to inform a future sample size calculation.
4. To understand the experiences of people with RTIs and primary care clinicians on point-of-care testing for respiratory viruses and biomarkers, and its effect on prescribing.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/11/2024, East of Scotland Ethic Committee (East of Scotland Research Ethics Service Tayside Academic Health Sciences Centre Residency Block Level 3 George Pirie Way Ninewells Hospital & Medical School, Dundee, DD1 9SY, United Kingdom; +44 1382 383839; TAY.eosres@nhs.scot), ref: 24/ES/0077

Study design
Randomized controlled interventional feasibility trial with no blinding

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Respiratory tract infections, antibiotic resistance

Interventions
Group 1 – A Covid/Flu lateral flow test will be performed using a nasal swab. This test takes around 10 mins to perform.
Group 2A – A Covid/Flu lateral flow test will be performed using a nasal swab. As well as this, FebriDx will also be performed. This test shows if the participant has elevated levels of CRP (an inflammatory biomarker indicative of a bacterial infection) or MxA (A marker of the antiviral immune response indicative of a viral infection).
Group 2B – A Covid/Flu lateral flow test will be performed using a nasal swab. As well as this, a SureScreen CRP test will be performed. This test shows if the participant has elevated levels of CRP (an inflammatory biomarker indicative of a bacterial infection) at three different levels – 10ug/l, 40ug/l, 80mg/l
Group 3 – Usual Care

All treatment is to be decided by the clinician and does not need to follow the advice of the tests. Both initial prescribing decision and final prescribing decision after the tests have been complete will be logged.

Randomisation is done using a program called sealed envelope. This is set up to stratify randomisation by the initial prescribing decision. The clinician simply needs to input patient ID, initial prescribing decision and if they are eligible for the study and they will be randomised.

The participant will need to complete a 28 day follow up diary. Everyday they will rank their symptoms from a list from a scale of 0-6 with 0 being not at all and 6 being very severe. Once a week, patients will note down if they have received any antibiotics or antivirals for their consulting chest infection, if they've seen a GO again, if they've been hospitalised, been to A&E or an out of hours centre. After 14 days, the first half of the diary will be returned by freepost envelope and the same again after 28 days with the latter half.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FebriDx, SureScreen Covid-19/Influenza A/B lateral flow dual cassette, SureScreen CRP Test

Primary outcome(s)
Feasibility outcome measures:
1. Recruitment rate is measured using screening and enrolment logs at monthly timepoints
2. Follow-up rate is measured using returned patient diaries at end of study
3. Withdrawals are measured using study records at end of study
4. Eligibility proportion is measured using screening logs at screening and summarised end of study
5. Compliance – valid test results is measured using CRFs at testing and summarised end of study
6. Compliance – correct number of tests is measured using CRFs at end of study
7. Clinician acceptability is measured using acceptability question in CRF at day of recruitment and summarised end of study

8. Participant acceptability is measured using acceptability question in CRF at day of recruitment and summarised end of study
9. Participant refusal rate is measured using screening logs at approach and summarised end of study

Key secondary outcome(s))
Exploratory outcome measures:
1. Antibiotic prescribing is measured using CRF at day of recruitment, within 28 days, and summarised end of study
2. Antiviral prescribing is measured using CRF at day of recruitment, within 28 days, and summarised end of study
3. Change in prescribing due to testing is measured using clinician CRFs at consultation and summarised end of study
4. Time to return to usual activities is measured using patient follow-up diaries recorded daily and summarised end of study
5. Re-consultations is measured using patient follow-up diaries within 28 days from consultation
6. Hospitalisations is measured using patient follow-up diaries within 28 days from consultation

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Age 65 years or over
2. Presenting to primary care with symptoms of a lower respiratory tract infection beginning less than seven days prior to appointment. Symptoms must include an acute cough and one other symptom:
2.1. Shortness of breath
2.2. Sputum
2.3. Chest pain
3. The ability to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinical diagnosis of pneumonia
2. Patient is already receiving antibiotics and/or antivirals or has used antibiotics/antivirals in the past 30 days.
3. Patient declines URT swabbing or finger prick blood testing.
4. Patient has cystic fibrosis
5. Patient has bronchiectasis
6. Patient is terminally ill
7. Patient is unable to comply with trial procedures
8. Patient has dementia, and/or is not able to consent themselves to trial procedures

Date of first enrolment
04/03/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Waterside Medical Practice
Elm Grove
Hayling Island
England
PO11 9AP

Study participating centre
The Swan Practice
North End Surgery
26 High Street
Buckingham
England
MK18 1NU

Study participating centre
St Bartholomew and Hollow Way Medical Pratice
St Bartholomew's Medical Centre, Manzil Way, Cowley Rd

Oxford
England
OX4 1XB

Study participating centre
Oaks Healthcare
30 London Rd, Cowplain
Waterlooville
England
PO8 8DL

Study participating centre
Didcot Health Centre Practice
Britwell Road
Didcot
England
OX11 7JH

Study participating centre
Hedena Health
207 London Road
Headington
Oxford
England
OX3 9JA

Study participating centre
Chawton Park Surgery
Chawton Park Road
Alton
England
GU34 1RJ

Study participating centre
Woodlands Medical Centre
Woodlands Road
Didcot
England
OX11 0BB

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Southampton Biomedical Research Centre

Alternative Name(s)
NIHR Southampton Biomedical Research Centre, NIHR Southampton BRC, Southampton Centre for Biomedical Research, NIHR SCBR, SCBR

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
As is standard, an “open as possible, closed as necessary” stance will be taken when it comes to data sharing.
Underlying data for the final thesis will be deposited in the institutional research repository via PURE. A DOI will be requested, and access will be agreed with the supervisory team.
Data will be licensed for reuse using a Creative Commons licence.
The data used will be cited in the final thesis under accompanying materials.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	05/11/2024	26/11/2025	No	Yes
Protocol file	version 1.3	28/10/2024	26/11/2025	No	No