

Improving antibiotic use for upper respiratory infections in GP practices

Submission date 29/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/12/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/09/2025	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Antibiotics only work for infections caused by bacteria. They do not work if the infection is caused by a virus. If antibiotics are given too often, they can stop working. When antibiotics stop working this is called antimicrobial resistance (AMR). This means infections caused by bacteria are difficult to treat and people might die. By 2050, AMR could cause more deaths than cancer. Using fewer antibiotics means less AMR. Most antibiotics are given in GP practices. The reason too many antibiotics are given is because it is often hard to tell if an infection is caused by bacteria or by a virus. Antibiotics are often given for infections caused by viruses, like sore throats and sinus infections. Infections in the ear, throat, nose or sinuses, but not the lungs, are known as upper respiratory infections. The UK government wants tests that can show if an infection is bacterial or viral. Quick tests, used close to where patients are seen, like GP practices, are called point-of-care tests (POCTs).

A new, quick POCT, called FebriDx®, uses a tiny 'finger-prick' blood sample to measure how a patient's immune system is reacting to the infection. The result can help healthcare staff know if the infection is viral or bacterial. This POCT has been used in hospitals, but not in GP practices. This study aims to find out if FebriDx® will work in GP practices.

Who can participate?

Patients aged 1 year and over with symptoms of upper respiratory infections

What does the study involve?

The researchers will invite GP practices to test adults and children with upper respiratory infections using FebriDx®. They want to know:

1. How often healthcare staff use the test and who they test
2. If the test changes what healthcare staff think caused the infection and whether antibiotics are needed
3. How good the test is at telling the difference between viral and bacterial infections

The researchers will interview patients, GPs, nurses and other staff to find out how they got on with the test.

What are the possible benefits and risks of participating?

If the test is practical, acceptable to patients, and may reduce antibiotic use, the researchers

plan to do a larger study to find out if this test can be used in all GP practices to help reduce antibiotic use and the amount of AMR.

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

When is the study starting and how long is it expected to run for?
September 2024 to August 2025

Who is funding the study?
NIHR School for Primary Care Research (UK)

Who is the main contact?
1. Dr Emily Brown, emily.brown@bristol.ac.uk
2. Dr Andrew Turner, andrew.turner@bristol.ac.uk

Study website
<https://rapidimmunetest.blogs.bristol.ac.uk/>

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

332965

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 63637

Study information

Scientific Title

Host immune response point-of-care testing for children and adults presenting to primary care with acute upper respiratory tract infection: a mixed-methods feasibility study

Acronym

RAPID IMMUNE TEST

Study objectives

To investigate the feasibility and value of FebriDx® use for children and adults with acute URTIs in primary care, and inform the design of a future randomised-controlled trial (RCT).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/10/2024, West of Scotland REC 4 (Research Ethics, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 24/WS/0109

Study design

Prospective feasibility cohort study with qualitative evaluation and exploration of diagnostic accuracy

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Acute upper respiratory tract infections (URTIs) in primary care

Interventions

The Host Response Point-Of-Care Test (POCT HR) device that we will use in this study is FebriDx® (Lumos Diagnostics), a novel combination POCT HR. FebriDx® has advantages for primary care use; it is dual-marker, hand-held, rapid turnaround (10 minutes) and does not require an additional desktop analyser. It is the only combination POCT HR using a 'finger-prick' (rather than venous) blood sample. It has indicators of both viral (myxovirus resistance protein A, MxA) and bacterial (CRP) host immune response.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

FebriDx Point-of-Care Test Device

Primary outcome measure

Clinician pre- and post-test diagnostic confidence measured using a clinician survey on case report forms completed before and after the FebriDx test is performed

Secondary outcome measures

1. Percentage of eligible patients in whom FebriDx® is used, measured using a patient identification form when potentially eligible patients present at their general practice
2. Clinical and demographic characteristics of patients in whom FebriDx® is used, measured using the pre-test case report form at the start of their consultation
3. Job type and number of staff using FebriDx® measured using the pre-test case report form at the start of each consultation

4. Distribution of FebriDx® results (viral/bacterial/negative/invalid) measured using a post-test case report form at the end of the consultation
5. Clinician pre- and post-test belief that antibiotic treatment is necessary, measured using a clinician survey on case report forms completed before and after the FebriDx test is performed
6. The proportion of patients prescribed antibiotics after FebriDx® measured using a post-test case report form at the end of the consultation
7. Sensitivity and specificity for acute bacterial URTI (TaqMan array analysis of nasal/throat swabs will enable assessment of microbial prevalence, burden and viral/bacterial diversity in the URT) at the end of the study
8. Re-consultation and antibiotic prescribing events within 30 days following study recruitment measured using a notes review case report form
9. Hospitalisations and death within 30 days following study recruitment measured using a notes review case report form

Overall study start date

01/09/2024

Completion date

13/08/2025

Eligibility

Key inclusion criteria

1. Age ≥ 12 months being assessed (face-to-face or remote, but willing to attend in person for study tests) for symptoms of acute (≤ 21 days) URTI as identified by the recruiting clinician, including sore throat/pharyngitis/laryngitis, acute middle ear infections (acute otitis media), sinusitis or cough but without symptoms or signs localising to the lower respiratory tract (shortness of breath, wheeze, sputum, chest pain)
2. The clinician has decided that they are likely to prescribe antibiotics in the absence of further diagnostic testing (to prevent over-medicalisation of URTIs)
3. Clinician and patient willing to wait for POCT result before finalising treatment plan

Participant type(s)

Patient, Other

Age group

Mixed

Lower age limit

1 Years

Sex

Both

Target number of participants

Planned Sample Size: 231; UK Sample Size: 231

Total final enrolment

249

Key exclusion criteria

1. Previously participated in this study
2. Age <12 months
3. Symptoms or signs of lower respiratory tract involvement, such as new shortness of breath, wheeze, sputum, chest pain
4. Present with symptoms >21 days
5. Patient unable to receive study tests from the GP practice before a prescribing decision is made
6. Current use of antibiotic or antiviral medication
7. Patients who are immunosuppressed
8. Live viral immunisation within the last 30 days
9. Adults lacking capacity to consent for themselves
10. Prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service
11. Study samples cannot be transported to laboratory to be received within 48 hours of being taken

Date of first enrolment

25/11/2024

Date of final enrolment

16/05/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

General practices in the NIHR South West Central Research Delivery Network area

United Kingdom

BS1 2NT

Sponsor information

Organisation

University of Bristol

Sponsor details

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Sponsor type

University/education

Website

<http://bristol.ac.uk/>

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Government

Funder Name

NIHR School for Primary Care Research

Alternative Name(s)

School for Primary Care Research, NIHR SPCR

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Patients and members of the public helped design this study, agreed it is worth doing and that the 'finger-prick' test was the right test to use. The researchers will work with this group to review study documents and decide how the study should progress and what the results mean.

The researchers will share their results with:

1. The public, using their website, social media and local events

2. The research community in scientific publications and at conferences
3. The NHS and policymakers

All results in journals and presentations will be anonymous. A summary of findings will be provided to participants, and study progress and results will be made available via appropriate websites and social media feeds. Further avenues for output may also be explored after consultation with PPI members.

Intention to publish date

31/08/2026

Individual participant data (IPD) sharing plan

The datasets generated during the study will be stored in a publicly available repository, through controlled access: <https://data.bris.ac.uk>

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 0.5	09/07/2024	03/12/2024	No	No