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Improving antibiotic use for upper respiratory infections in GP practices

Submission date
29/11/2024

Recruitment status
No longer recruiting

Registration date
10/12/2024

Overall study status
Completed

Last Edited
03/09/2025

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
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
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
332965

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FebriDx Point-of-Care Test Device

Primary outcome(s)
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

Key secondary outcome(s))
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 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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 years

Sex
All

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
United Kingdom

England

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

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.5	09/07/2024	03/12/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes