

# Rapid respiratory microbiological point-of-care-testing in primary care (RAPID-TEST trial)

<b>Submission date</b> 21/10/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/11/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/06/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In the UK, GPs treat over 50% of respiratory tract infections (RTIs) with antibiotics despite strong evidence that the majority of patients do not benefit. Antibiotics can have side effects and unnecessary overuse leads to antimicrobial resistance which is a top 10 threat to global public health. One potential solution is use of point-of care-tests (POCT) which are medical tests conducted at the time and place of patient care. Rapid respiratory point-of-care-tests (POCTRM) could be used to inform antibiotic prescribing decisions.

This is a multi-centre, individually randomised controlled trial to determine whether respiratory microbiological point-of-care-tests (POCTRM) reduce same day antibiotic prescribing and modify clinician and patient beliefs about the need for antibiotics. The trial aims to recruit 514 participants from up to 16 GP practices across England.

### Who can participate?

Patients aged  $\geq 12$  months presenting to their GP practice for a suspected respiratory infection where the Study Clinician and/or participant believe antibiotic treatment is, or may be, necessary will be invited to take part.

### What does the study involve?

A swab of the nose and throat will be taken from participants using standard kits provided. Participants will be individually randomised 1:1 to intervention (GP POCTRM Test) or control (No GP POCTRM Test). For participants randomised to GP POCTRM Test, a portion of the swab sample will be analysed immediately at the GP practice using the POCTRM machine. The time for processing one swab to results being available is approximately 1 hour.

The remaining swab sample from participants in the intervention arm and the whole swab sample from participants in the control arm will be transferred within 24 hours to the central research laboratory. The central lab will repeat testing using the POCTRM machine and will also conduct extended testing for respiratory viruses and bacteria.

The Study Clinician will be informed of the participant's allocated group immediately after randomisation. For participants randomised to GP POCTRM Test, the Study Clinician will need to wait to receive the POCTRM result before deciding whether any treatment is required. For participants randomised to No GP POCTRM Test, decisions can proceed immediately.

Participants will be asked to complete a Trial Diary for up to 28 days or until symptoms resolve, whichever is sooner. They will also be sent a 2-month follow up questionnaire.

What are the possible benefits and risks of participating?

For participants in the group allocated to receiving the POCTRM results, those results may help the GP decide whether an antibiotic is required to treat their respiratory tract infection. Some people find taking part in research rewarding and may benefit from the extra contact from being part of the trial. Involvement in the trial may help to inform future treatment recommendations for patients with respiratory tract infections.

Participating in this trial will mean taking time out of normal activities to allow the trial research team to collect information from participants about their respiratory tract infection. The trial research team will also need to collect information about participant's views at three separate points during the day that they present to their GP. Participants may need to wait longer than usual for the GP to make a decision about whether any antibiotic treatment will be prescribed. Participants will also need to spend a couple of minutes every day completing the Trial Diary for up to 28 days and a couple of minutes completing the 2-Month Questionnaire.

Where is the study run from?

University of Bristol (UK)

When is the study starting and how long is it expected to run for?

April 2022 to May 2025

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?

Prof. Alastair Hay, [rapidtest-study@bristol.ac.uk](mailto:rapidtest-study@bristol.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Prof Alastair Hay

### ORCID ID

<https://orcid.org/0000-0003-3012-375X>

### Contact details

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rapidtest-study@bristol.ac.uk

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

299647

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

CPMS 53931, NIHR131758, IRAS 299674

## Study information

### Scientific Title

Rapid respiratory microbiological point-of-care-testing in primary care: a randomised controlled efficacy trial with internal pilot and qualitative and quantitative investigation of microbial, behavioural and antibiotic mechanisms (the RAPID-TEST RCT)

### Acronym

RAPID-TEST

### Study objectives

Use of a rapid respiratory microbiological point-of-care-test (POCTRM), for suspected respiratory tract infections (RTIs) in primary care, will reduce same-day antibiotic prescribing.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 11/10/2022, (), ref: 22/NW/0294

### Study design

Interventional randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

GP practice

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

## **Health condition(s) or problem(s) studied**

Respiratory infection

## **Interventions**

Participants will need to provide a nose and throat swab sample. Participants will be individually randomised 1:1 to intervention (GP POCTRM test) or control (No GP POCTRM test) using an internet-based randomisation system developed and maintained by Sealed Envelope™. For participants randomised to the GP POCTRM Test group, a portion of their swab sample will be analysed immediately using the BioFire® FilmArray® Torch 1 machine. The remaining swab sample from participants in the GP POCTRM Test group and the whole swab sample from participants in the No GP POCTRM Test group will be transferred within 24 hours to the central research laboratory.

For participants randomised to GP POCTRM Test, the Study Clinician will wait to receive the result of the POCTRM before deciding whether any antibiotic treatment is required. For participants randomised to No GP POCTRM Test, a decision on whether antibiotic treatment is required can be made immediately.

## **Intervention Type**

Other

## **Primary outcome measure**

Antibiotic prescribing (including delayed prescribing) for a RTI at Appointment Two

## **Secondary outcome measures**

1. Mean symptom severity on Days 2 to 4; Timepoint(s): Days 2 to 4;
2. Participant Views; Timepoint(s): Day 1 and 2 Months;
3. Last day on which any symptom was recorded as "moderately bad" or worse; Timepoint(s): Up to Day 28;
4. Length of time to return to usual activities; Timepoint(s): Up to Day 28;
5. Last day prior to all symptoms recorded as zero for two consecutive days ; Timepoint(s): Up to Day 28;
6. Any new symptoms or worsening of pre-existing symptoms ; Timepoint(s): Up to Day 28;
7. Documentation of any RTI related consultation (in and out of normal office hours) after Appointment Two and  $\leq 28$  days, whether for the same symptoms /illness as the recruitment consultation with/out documentation that symptoms are getting worse; Timepoint(s): Up to Day 28;
8. Evidence of any hospital admission for a respiratory infection in the medical records  $\leq 28$  days; Timepoint(s): 2 Months;
9. Name, strength, frequency and quantity of antibiotics and antivirals prescribed after Appointment Two and  $\leq 28$  days; Timepoint(s): 2 Months;
10. Name of antibiotic and antiviral, and number of times per day the medicine was consumed; Timepoint(s): Up to Day 28;
11. Documentation of any consultation (in and out of normal office hours)  $\leq 6$  months for a RTI;

Timepoint(s): 6 months;

12. Participant responses to qualitative questions; Timepoint(s): During optional interview;

13. Discrete choice experiment (DCE) survey ; Timepoint(s): During optional survey;

14. Clinician responses to qualitative questions; Timepoint(s): During optional interview;

15. Clinician DCE survey; Timepoint(s): During optional survey;

16. Clinician views; Timepoint(s): Day 1;

17. Central research laboratory POCTRM result; Timepoint(s): By end of trial;

18. Central research laboratory extended testing ; Timepoint(s): By end of trial;

19. EQ-5D-5L and EQ-5D-Y ; Timepoint(s): Up to Day 28

## **Overall study start date**

01/04/2022

## **Completion date**

31/05/2025

# **Eligibility**

## **Key inclusion criteria**

1. Aged  $\geq 12$  months on the day of presentation to primary care.
2. Presenting to primary care for the first time in this episode, and within 21 days of illness onset, with a Study Clinician suspected acute respiratory infection. Symptoms may include one or more of:
  - 2.1. Sore throat
  - 2.2. Runny nose
  - 2.3. Earache
  - 2.4. Cough
  - 2.5. Sputum
  - 2.6. Wheeze
  - 2.7. Shortness of breath
3. Study Clinician diagnoses of an upper or lower RTI such as:
  - 3.1. Acute otitis media
  - 3.2. Acute sinusitis
  - 3.3. Acute pharyngitis or tonsillitis
  - 3.4. Sore throat
  - 3.5. Acute laryngitis
  - 3.6. Acute cough
  - 3.7. Acute bronchitis
  - 3.8. Chest infection
  - 3.9. Acute lower RTI
  - 3.10. Infective exacerbation of chronic lung disease e.g. asthma, chronic obstructive pulmonary disease (COPD), emphysema or bronchiectasis
4. Study Clinician or patient/parent/carer believes antibiotic treatment is, or may be, necessary (either Study Clinician or patient/parent/carer must answer "strongly agree", "agree" or "neither agree nor disagree" to the question about beliefs on use of antibiotics to treat this illness).
5. Patient/parent/carer willing and able to give informed consent
6. Patient/parent/carer willing to have a nasal and throat swab taken, or willing and able to collect, self-take and promptly return the swab to the site
7. Study Clinician and patient/parent/carer willing to wait for the POCTRM result before an antibiotic prescribing decision is made
8. Laboratory transport pick up for samples expected  $< 24$  hours e.g. sample is expected to be

ready prior to final sample collection on a Friday

9. Patient/parent/carer willing to complete Trial Diary and for outcome data to be collected from medical record

**Participant type(s)**

Patient

**Age group**

Mixed

**Lower age limit**

12 Months

**Sex**

Both

**Target number of participants**

Planned Sample Size: 514; UK Sample Size: 514

**Key exclusion criteria**

1. Patient known to have cystic fibrosis
2. Patient requires hospital admission
3. Previous participation in the current RAPID-TEST trial
4. Participation in another study of RTI  $\leq$  6 weeks prior to randomisation

**Date of first enrolment**

14/11/2022

**Date of final enrolment**

30/09/2024

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Nightingale Valley Practice**

Wick Road

Bristol

United Kingdom

BS4 4HU

**Study participating centre**

**Whiteladies Medical Group**

Whiteladies Health Centre  
Whatley Road  
Clifton  
Bristol  
United Kingdom  
BS8 2PU

**Study participating centre****Mendip Vale Medical Practice**

Langford Surgery  
Pudding Pie Lane  
Langford  
Bristol  
United Kingdom  
BS40 5EL

**Study participating centre****Phoenix Health Group**

Phoenix Cirencester  
9 Chesterton Lane  
Cirencester  
United Kingdom  
GL7 1XG

**Study participating centre****Clevedon Medical Centre**

Old Street  
Clevedon  
United Kingdom  
BS21 6DG

**Study participating centre****Streamside Surgery**

Eastland Road  
Thornbury  
Bristol  
United Kingdom  
BS35 1DP

**Study participating centre**

**Hartwood Healthcare**

Hareclive Road  
Bristol  
United Kingdom  
BS13 0JP

**Study participating centre****Prices Mill Surgery**

Newmarket Road  
Nailsworth  
Stroud  
United Kingdom  
GL6 0DQ

**Study participating centre****Heart of Bath**

45 Upper Oldfield Park  
Bath  
United Kingdom  
BA2 3HT

**Study participating centre****Close Farm Surgery**

47 Victoria Road  
Warmley  
North Common  
Bristol  
United Kingdom  
BS30 5JZ

**Study participating centre****Severnside Medical Practice**

Quayside House  
Quay Street  
Gloucester  
United Kingdom  
GL1 2TZ

**Study participating centre****Hathaway Surgery**

32 New Road



Chippenham  
United Kingdom  
SN15 1HP

**Study participating centre**  
**Stafford Medical Group**  
Locking Castle Medical Centre  
Highlands Lane  
Weston-super-mare  
United Kingdom  
BS24 7DX

**Study participating centre**  
**Harbourside Family Practice**  
The Marina Healthcare Ctr  
2 Haven View  
Portishead  
Bristol  
United Kingdom  
BS20 7QA

**Study participating centre**  
**Hope House Surgery**  
Hope House Centre  
10 Waterloo Road  
Radstock  
United Kingdom  
BA3 3EP

**Study participating centre**  
**West Walk Surgery**  
Yate West Gate Centre  
21 West Walk  
Bristol  
United Kingdom  
BS37 4AX

## **Sponsor information**

**Organisation**

University of Bristol

**Sponsor details**

Research & Enterprise Division  
Second Floor, Augustines Courtyard  
Orchard Lane  
Bristol  
England  
United Kingdom  
BS1 5DS  
+44 117 4556247  
research-governance@bristol.ac.uk

**Sponsor type**

University/education

**Website**

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

**ROR**

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

**Funder(s)****Funder type**

Government

**Funder Name**

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

**Results and Publications****Publication and dissemination plan**

The aim will be to publish our primary manuscript in a high impact medical journal, and present our findings at medical conferences. We will also write a full report for the NIHR.

**Intention to publish date**

30/05/2026

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

**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="#">Protocol file</a>	version 2.0	04/10/2022	07/11/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>			20/05/2024	Yes	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	02/09/2024	10/09/2024	No	No
<a href="#">Protocol file</a>	version 3.0	06/03/2023	25/10/2024	No	No
<a href="#">Protocol file</a>	version 4.0	01/02/2024	25/10/2024	No	No
<a href="#">Protocol file</a>	version 5.0	05/07/2024	25/10/2024	No	No
<a href="#">Protocol file</a>	version 6.0	12/09/2024	25/10/2024	No	No
<a href="#">Results article</a>	Secondary outcome qualitative study using semistructured interviews	25/06/2025	27/06/2025	Yes	No