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

Submission date
21/10/2022

Recruitment status
No longer recruiting

Registration date
08/11/2022

Overall study status
Completed

Last Edited
27/06/2025

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 >=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

Contact information

Type(s)
Scientific

Contact name
Prof Alastair Hay

ORCID ID
https://orcid.org/0000-0003-3012-375X

Contact details
Population Health Sciences
Bristol Medical School
University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom

BS8 2PS
+44 1179287376
rapidtest-study@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
299647

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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 ≤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 ≤28 days; Timepoint(s): 2 Months;
9. Name, strength, frequency and quantity of antibiotics and antivirals prescribed after Appointment Two and ≤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) ≤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

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Aged >=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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 months

Sex
All

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 < = 6 weeks prior to randomisation

Date of first enrolment
14/11/2022

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
United Kingdom

England

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

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Government

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

Results and Publications

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?
Results article	Secondary outcome qualitative study using semistructured interviews	25/06/2025	27/06/2025	Yes	No
Protocol article		20/05/2024	22/05/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	04/10/2022	07/11/2022	No	No
Protocol file	version 3.0	06/03/2023	25/10/2024	No	No
Protocol file	version 4.0	01/02/2024	25/10/2024	No	No
Protocol file	version 5.0	05/07/2024	25/10/2024	No	No
Protocol file	version 6.0	12/09/2024	25/10/2024	No	No
Statistical Analysis Plan	version 1.0	02/09/2024	10/09/2024	No	No