

Respiratory viral testing in the management of febrile infants presenting to Emergency care: A pilot study

Submission date 09/10/2026	Recruitment status Not yet recruiting	☒ Prospectively registered ☐ Protocol
Registration date 15/10/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 14/10/2026	Condition category Infections and Infestations	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Fever is a common reason for young infants to attend an Emergency Department (ED). In babies under 90 days old, a fever can sometimes be a sign of a serious infection, such as meningitis or sepsis. For this reason, young babies with a fever may undergo tests such as blood tests or a lumbar puncture, where a needle is inserted into the lower back to collect a sample of fluid from around the spinal cord. Many babies are also given antibiotics and admitted to hospital. However, fever in young babies is often caused by a viral infection that does not require antibiotics or invasive tests. Recent evidence suggests that testing for viruses using a simple nose or throat swab may help doctors identify babies who are less likely to have a serious bacterial infection.

Rapid viral tests can provide results within approximately one hour. The REFINE study will investigate whether rapid testing for three common viruses, Respiratory Syncytial Virus (RSV), SARS-CoV-2 (COVID-19) and influenza (flu), could help reduce the number of invasive tests performed, antibiotic use, time spent in the Emergency Department and hospital admissions. The longer-term aim is to carry out a larger UK-wide trial. Before doing this, a smaller pilot study is needed to find out whether a larger trial can be successfully delivered. The pilot will look at how many families are willing to take part, how healthcare professionals use the rapid viral test, and whether the test appears to affect babies' care.

The study will also explore the views and experiences of parents or caregivers and healthcare professionals regarding rapid viral testing and participation in the research.

Who can participate?

Infants aged between 29 and 90 days who attend hospital with a fever greater than 38°C.

What does the study involve?

Babies taking part will be randomly allocated to one of two groups:

- Usual care group: Babies will receive the usual care provided by the clinical team, without the rapid viral test being used as part of the study.

- **Rapid viral testing group:** Babies will receive usual care and will also have a rapid viral test for RSV, COVID-19 and flu using a nose or throat swabs.

The rapid viral test provides a result within approximately one hour.

Apart from the rapid viral test, the study will not change the care babies receive. Decisions about investigations, treatment, antibiotics and hospital admission will continue to be made by the doctors and nurses looking after the baby.

The research team will collect information to help determine whether a larger UK-wide trial would be possible. This will include information about recruitment, how the rapid test is used by healthcare professionals, and whether it may affect tests, treatment, time spent in the Emergency Department or hospital admission.

Parents or caregivers and healthcare professionals will also be asked about their views and experiences of the rapid viral test and the study.

What are the possible benefits and risks of participating?

There may be no direct benefit to babies taking part in this pilot study. However, the information collected will help researchers understand whether rapid viral testing could be used in a larger UK study investigating whether it can safely reduce invasive procedures, antibiotic use, time spent in the Emergency Department and hospital admissions for young babies with fever.

For babies allocated to the rapid viral testing group, the test involves taking a swab from the nose or throat. This may cause brief discomfort or distress.

Where is the study run from?

The REFINE pilot study will be run at Cardiff and Vale University Health Board and the study is being coordinated by Cardiff University Clinical Trial Unit.

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

November 2026 and run until June 2027.

Who is funding the study?

Health and Care Research Wales

Who is the main contact?

Angela Strang, REFINE@cardiff.ac.uk

Contact information

Type(s)

Public

Contact name

Ms Angela Strang

Contact details

Children and Young Adults Research Unit,
University Hospital of Wales
Cardiff
United Kingdom
CF14 4XW

+44 (0)2921841615
REFINE@cardiff.ac.uk

Type(s)

Scientific, Principal investigator

Contact name

Dr Joanne Euden

Contact details

Centre for trials Research
7th floor, Neaudd Meirionnydd
Cardiff University
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 (0)2922510771
eudenj@cardiff.ac.uk

Additional identifiers**Integrated Research Application System (IRAS)**

372637

Health and Care Research Wales Integrated Funding Scheme Project Ref

03-TC-24-20 - Dr Jordan Evans

Study information**Scientific Title**

Respiratory viral testing in the management of Febrile Infants presenting to Emergency care

Acronym

REFINE

Study objectives

To conduct a quantitative assessment of the ability to screen, recruit and randomise young febrile infants to respiratory viral POCT or usual care.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 21/08/2026, East of England - Cambridge South Research Ethics Committee (Equinox House City Link Nottingham, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8241; cambridgesouth.rec@hra.nhs.uk), ref: 26/EE/0179

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Screening

Study type(s)**Health condition(s) or problem(s) studied**

Respiratory viral testing in the management of febrile infants presenting to emergency care

Interventions

REFINE is an external pilot, open-label, individually randomised controlled trial with two parallel arms with embedded process and economic evaluation, comparing standard of care in babies with fever presenting to Emergency Department (ED) with standard care plus the addition of a point-of-care respiratory viral test (POCT). This will determine whether the fever is due to a virus or the possibility of an Invasive bacterial infection. Babies presenting to the ED with fever will be assessed according to standard local care and prospectively enrolled and randomised into either the standard care arm or interventional arm of the REFINE trial once the eligibility criteria have been checked. The method of randomisation uses a computerised web-based randomisation process will be integrated into the REDcap database and randomisation will be at 1:1 allocation. They will receive treatment as per standard care with/without the addition of a nasal or throat swab to be used in a POCT. The result of the test may aid the treating clinician in the clinical management of the baby and to decide whether to proceed with more invasive procedures (i.e. a lumbar puncture) to determine the origin of fever.

The trial uses commercially available POCT devices for testing including but not limited to the Abbott ID Now and Roche Liat devices as described in the trial protocol. Initial approaches to obtain informed consent will be made as soon as practically possible, and as soon as the emergency has passed. Babies will be assessed up to day 7, or discharge, with follow-up 7 days post discharge by review of medical records. REFINE will also include an embedded process and economic evaluation, which will seek to identify implementation barriers and key cost drivers to inform a large-scale effectiveness evaluation. The trial will be undertaken at two NHS hospitals in Wales (University Hospital of Wales - Cardiff and Vale University Health Board, and Princess of Wales Hospital - Cwm Taf Morgannwg Health Board).

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Abbott ID NOW POC

Primary outcome(s)

1. Number of potential participants screened measured using data recorded in the screening log at screening and throughout the duration of the trial
2. Number of participants recruited measured using data review of information record in the electronic Case Report Forms (eCRF) at screening and throughout the duration of the trial
3. Proportion randomised from those screened and recruited measured using data review on the proportion randomised and undergoing the test at randomisation
4. Follow-up rates at 7 days / completeness of data measured using data review of from medical records at follow-up at 7 days

Key secondary outcome(s)

1. Parent/caregiver reported qualitative feedback on acceptability of the intervention measured using semi-structured interviews at a single time point up to 28 days post randomisation
2. Parent/caregiver reported qualitative feedback on acceptability of the research process measured using semi-structured interviews at a single time point up to 28 days post randomisation
3. Healthcare professional reported qualitative feedback on acceptability of the intervention measured using semi-structured interviews at a single time point
4. Healthcare professional reported qualitative feedback on acceptability of the research process measured using semi-structured interviews at a single time point
5. Clinician reported qualitative feedback on respiratory viral POCT influence on clinical decision making measured using a qualitative interview at a single time point

Completion date

30/06/2027

Eligibility**Key inclusion criteria**

1. Infants aged 29 - 90 days with fever $\geq 38.0^{\circ}\text{C}$ (Fever $\geq 38^{\circ}\text{C}$ recorded in ED or in preceding 24 hours by any thermometer)

Healthy volunteers allowed

No

Age group

Child

Lower age limit

29 Days

Upper age limit

90 Days

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Infants born at <32 weeks' gestation
2. Discharged from hospital more than 7 days after birth
3. Required re-admission to hospital after birth for more than 24 hours and received parenteral antibiotics
4. Nasopharyngeal surgery
5. Infants with a focal bacterial infection (eg, cellulitis, septic arthritis, osteomyelitis) or clinical bronchiolitis

Date of first enrolment

01/11/2026

Date of final enrolment

30/06/2027

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Cardiff & Vale University Lhb

Woodland House

Maes-y-coed Road

Cardiff

Wales

CF14 4HH

Study participating centre

Cwm Taf Morgannwg University Local Health Board

Dewi Sant Hospital

Albert Road

Pontypridd
Wales
CF37 1LB

Sponsor information

Organisation

Cardiff and Vale University Health Board

ROR

<https://ror.org/0489f6q08>

Funder(s)

Funder type

Funder Name

Health and Care Research Wales

Alternative Name(s)

Health & Care Research Wales, Health Care Research Wales, Ymchwil lechyd a Gofal Cymru, HCRW

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available