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Surveillance towards preventing RSV respiratory infection in paediatrics

Submission date
28/07/2022

Recruitment status
No longer recruiting

Registration date
08/08/2022

Overall study status
Completed

Last Edited
23/05/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Respiratory Syncytial Virus (RSV) infection is very common particularly in the winter, in most children this leads to mild disease but it can also lead to a lower respiratory tract infection commonly known as bronchiolitis. As many as 4 children per 100 are admitted to hospital each year. About 10% of all Paediatric Intensive Care Unit (PICU) admissions (over 1000 children a year) are admitted to Intensive Care in England. Each year about 20 young children die from this condition. RSV rapidly spreads to others including staff and patients requiring barrier nursing in wards and PICU. Very young children under 3 years of age, in particular those with other health conditions, are more vulnerable to severe infection.
At present, there is very limited surveillance information on laboratory-confirmed RSV, particularly in the community setting. There is also a lack of data on health economics, for example, the burden on the family and health care. Parents may lose income during their child's hospitalization, they may travel even 100 miles for intensive care, hospital beds are blocked each winter resulting in other care such as surgery being cancelled, or children being transferred to other cities for intensive care.
The main aim of this study is to assess the number of children with respiratory symptoms with laboratory-confirmed RSV swabs under 3 years of age in primary and secondary/tertiary healthcare settings in Merseyside, Chester and Bristol (United Kingdom). The study will also determine the health economic burden on the family and health care.

Who can participate?
Infants and children aged under 3 years who present to primary or secondary/tertiary healthcare with symptoms of a lower respiratory tract infection (LRTI)

What does the study involve?
Hospital-based surveillance will be conducted at Alder Hey Children's Hospital, the Women's Hospital in Liverpool and the Bristol Royal Hospital for Children (Bristol). General practice-based surveillance will be conducted in Liverpool and Wirral in Merseyside. Other sites may be included later in this study. Surveillance will be conducted from October 2021 until 2023. Parents will be asked to consent for a swab to be taken from the child's nose. The laboratory PCR test will then confirm whether they have RSV, other viruses or bacteria including influenza, SARS-Cov2 and Streptococcus pneumoniae. Medical records will provide demographics and medical background

information. Questionnaires for parents may be conducted 14 +/- 28 days after study enrolment to assess the clinical outcome of the infection, health care use and the economic burden to the family. In future: these data will contribute to informing vaccination strategies to prevent bronchiolitis.

What are the possible benefits and risks of participating?
There is a minimal direct benefit to participants when taking part in the study. If they are being seen in a GP clinic they will get the opportunity for a face-to-face clinical assessment when they may not have been offered one. Parents/guardians may benefit from a better understanding of clinical research; they may also benefit from a sense of making a valuable contribution to medical research.
The nasal swab may cause mild discomfort. The researchers will scavenge samples (retrieve the remaining sample after clinical analysis) from the laboratory if it was collected for clinical care whenever possible. The nasopharyngeal sample (of the top part of the throat) causes moderate discomfort there this will only be collected if this is required by the clinical team. Sampling may cause discomfort, irritation of the nose or nasopharynx, and possibly cause nosebleeds, although these are very uncommon.

Where is the study run from?
Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
November 2021 to May 2023

Who is funding the study?
Sanofi Pasteur (France)

Who is the main contact?
Lauren McLellan, stoprsv@lstmed.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
304483

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 304483, CPMS 50976

Study information

Scientific Title
Surveillance towards preventing paediatric: incidence RSV attributable (lower respiratory tract infection) in primary and secondary/tertiary healthcare settings in Merseyside and Bristol, UK

Acronym
STOP RSV

Study objectives
The main aim of this observational surveillance study is to assess the number of children with respiratory symptoms with laboratory-confirmed Respiratory Syncytial Virus (RSV) swabs under 3 years of age in primary and secondary/tertiary healthcare settings in Merseyside and Bristol (United Kingdom). The study will also determine the health economic burden to the family and health care.

RSV infection is very common particularly in the winter, in most children this leads to mild disease but it can also lead to a lower respiratory tract infection commonly known as bronchiolitis. As many as 4 children per 100 are admitted to hospital each year. Approximately 10% of all Paediatric Intensive Care Unit (PICU) admissions (over 1000 children a year) are admitted to Intensive Care in England. Each year approximately 20 young children die from this

condition1. RSV rapidly spreads to others including staff and patients requiring barrier nursing in wards and PICU2. Very young children <3 years of age in particular those with other health conditions are more vulnerable to severe infection.

At present there is very limited surveillance information with laboratory-confirmed RSV, particularly in the community setting. Also, there is a lack of data on health economics for example the burden on the family and health care. Parents may lose income during their child's hospitalization, they may travel even 100 miles for intensive care, hospital beds are blocked each winter resulting in other care such as surgery frequently cancelled, or children transferred to other cities for intensive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2021, West of Scotland Research and Ethics 4 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 21/WS/0142

Study design
Observational surveillance study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Respiratory syncytial virus (RSV)

Interventions
Current interventions as of 23/01/2023:
The main study is an observational surveillance study of the incidence and burden of RSV attributable to lower respiratory tract infection (LRTI) in children <3 years of age in primary and secondary/tertiary healthcare settings in Merseyside, Cheshire and Bristol.

A sub-study will be recruited in primary care to assess the burden of upper respiratory tract infection (URTI) attributable to RSV in Primary Care in Liverpool.

Adaptive design: following an interim analysis of the sub-study URTI population (n = 180 to 200) recruited over a minimum of 3 months. the inclusion criteria may be revised to increase the proportion of study participants with URTI as opposed to being limited to LRTI. If this exploratory cohort indicates a higher proportion of URTI-only participants are RSV positive, then the eligibility for all recruitment in primary care may be revised. Standard follow-up questionnaires will only be required for children who are RSV + or seek further health care including A&E or are hospitalised. The others will have a shorter questionnaire or telephone call/ email to parents to confirm if they require further health care.

Methods: hospital-based surveillance will be conducted at Alder Hey (AH) Children's Hospital, the Women's Hospital in Liverpool and the Bristol Royal Hospital for Children (Bristol), Countess

of Chester and Arrow Park. General practice-based surveillance will be conducted in Liverpool and Wirral in Merseyside. Other sites may be included later in this study. Surveillance will be conducted from October 2021 until 2023. The target is a minimum of 1800 children <3 years of age that meet the inclusion criteria.

Parents will be asked to consent for a swab to be taken from the nose of a child <3 years of age with symptoms. The laboratory PCR test will then confirm whether they have RSV, other viruses or bacteria including influenza, SARS-Cov2 and Streptococcus pneumoniae. Medical records will provide demographics and medical background information. Questionnaires for parents may be conducted 14 +/- 28 days after study enrolment to assess the clinical outcome of the infection, health care use and economic burden to the family.

Previous interventions:
The main study is an observational surveillance study of the incidence and burden of RSV attributable to lower respiratory tract infection (LRTI) in children <3 years of age in primary and secondary/tertiary healthcare settings in Merseyside and Bristol.

A sub-study will be recruited in primary care to assess the burden of upper respiratory tract infection (URTI) attributable to RSV in Primary Care in Liverpool.

Adaptive design: following an interim analysis of the sub-study URTI population (n = 180 to 200) recruited over a minimum of 3 months. the inclusion criteria may be revised to increase the proportion of study participants with URTI as opposed to being limited to LRTI. If this exploratory cohort indicates a higher proportion of URTI-only participants are RSV positive, then the eligibility for all recruitment in primary care may be revised. Standard follow-up questionnaires will only be required for children who are RSV + or seek further health care including A&E or are hospitalised. The others will have a shorter questionnaire or telephone call/ email to parents to confirm if they require further health care.

Methods: hospital-based surveillance will be conducted at Alder Hey (AH) Children's Hospital, the Women's Hospital in Liverpool and the Bristol Royal Hospital for Children (Bristol). General practice-based surveillance will be conducted in Liverpool and Wirral in Merseyside. Other sites may be included later in this study. Surveillance will be conducted from October 2021 until 2023. The target is a minimum of 1800 children <3 years of age that meet the inclusion criteria.

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Intervention Type
Other

Primary outcome(s)
Point prevalence (95% confidence intervals) of RSV-positive nasal swabs measured by PCR at baseline

Key secondary outcome(s))

1. Frequency and proportion of positive cases presenting in each category of health care using data searches to determine any lab-confirmed RSV cases reported at the individual sites during the period of recruitment to the study
2. Detection of other respiratory pathogens including influenza A/B, SARS-CoV2, and S. pneumoniae by PCR test on a nasal swab taken at baseline
3. Demographic data, medical history, baseline observations, severity of illness score, and health care utilisation in relation to URTI/LRTI symptoms prior to recruitment, measured using data collected at baseline
4. Data collected from medical records and questionnaires on days 14 and 28:
4.1. Proportion of participants with ongoing symptoms
4.2. Hospital duration (days) (median interquartile range [IQR])
4.3. Level of care (emergency department [ED]/ward/high dependency unit (HDU)/paediatric intensive care unit [PICU])
4.4. Duration and type of respiratory support (days) (median IQR)
4.5. Frequency of radiological assessments: x-rays etc
4.6. Frequency of GP or other primary care visits
4.7. Quality of life measured using PEDS QL and EQ-5D-3L
5. Health care data from existing metrics on the impact and opportunity costs of RSV over the peak winter RSV season from October to March at Alder Hey Children's Hospital:
5.1. Number of cancelled elective cases
5.2. Seasonal reduction in bed availability (number of bed days lost due to increase in respiratory infection cases)
5.3. Number of episodes children with respiratory symptoms are transferred to or retrieved from other PICUs
6. Existing health care data (anonymised) using data codes (HES/PICANET/ICD and SNOMED codes) for respiratory infection in children under age 3 years at recruiting sites during the period of recruitment to the study:
6.1. Primary care sites: the number of RTI and LRTI presenting at telephone consultations or GP appointments
6.2. Hospital sites:
6.2.1. Number of RSV laboratory-confirmed cases for inpatients
6.2.2. Number of admissions or emergency department attendances due to respiratory infection

Completion date
31/05/2023

Eligibility

Key inclusion criteria
Infants and children aged <3 years who present to primary or secondary/tertiary healthcare with symptoms of LRTI

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
3 years

Sex
All

Total final enrolment
2074

Key exclusion criteria
If they have already been to recruited to the study prior to 30 days

Date of first enrolment
12/12/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Royal Hospital for Children
University Hospitals Bristol and Weston NHS Foundation Trust
Paul O'Gorman Building
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Alder Hey Children's Hospital
East Prescot Road
Liverpool
United Kingdom
L14 5AB

Study participating centre
North West Coast Sites Clinical Research Network
iC1 Liverpool Science Park

131 Mount Pleasant
Liverpool
United Kingdom
L3 5TF

Study participating centre
Central Liverpool Primary Care Network
111-117 Limekiln Lane
Liverpool
United Kingdom
L5 8XR

Study participating centre
Marine Lake/Estuary Medical Practice
The Concourse
Grange Rd
West Kirby
United Kingdom
CH48 4HZ

Study participating centre
St Georges Medical Centre
Field Road
New Brighton
United Kingdom
CH45 5LN

Study participating centre
Fulwood Green Medical Centre
2A Jericho Lane
Liverpool
United Kingdom
L17 5AR

Study participating centre
Walk-in Centre Smithdown Road
Smithdown Rd
Liverpool
United Kingdom
L15 2LQ

Study participating centre
Arrowe Park Hospital (site)
Arrowe Park Hospital
Arrowe Park Road
Wirral
United Kingdom
CH49 5PE

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Industry

Funder Name
Sanofi Pasteur

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No