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Investigating the impact of the coronavirus (COVID-19) pandemic on children presenting to emergency departments across Europe

Submission date
06/07/2020

Recruitment status
No longer recruiting

Registration date
14/07/2020

Overall study status
Completed

Last Edited
03/09/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Ever since the first cases of SARS-CoV-2 were reported in Europe, and since the initial outbreak in Italy in February 2020, the pandemic has caused significant challenges for health care systems and the societies at large across Europe.

One of the few reassuring aspects of this pandemic might be that children don't appear to get infected as often as adults, that severe disease in children is rare, and that children appear to play a limited role in the transmission of the virus. As a result, numbers of children attending hospital emergency departments have been reported to have fallen drastically. However, the reduced numbers appear to be out of keeping with what was to be expected as a result of the government 'lockdown' policies. It is thought that, as a result of the imposed restrictions on free movements by governments, children are not cross-infecting one another with other common childhood diseases with the closure of daycare facilities and schools, that they are less exposed to air pollution triggering the respiratory disease, and that they are less often involved in high velocity, traffic-related trauma.

Also, as an unwanted effect of the pandemic, frontline clinicians are noticing an increase in delayed presentations of children with serious illness. Furthermore, cases of children presenting with an emerging Paediatric Inflammatory Multisystem Syndrome - temporally associated with Sars-Cov-2 (PIMS-TS) have been reported, with some of these children testing positive and some testing negative for SARS-CoV-2. At present, no there is no evidence to confirm these findings across multiple European countries. Therefore, it is important to describe current patterns of children presenting to paediatric emergency departments across Europe and compare these with historical data. The aim of this is to provide evidence for changes to attendance to emergency departments for children; to monitor for possible new diseases; and to understand the timeliness of their presentations in relation to the disease severity, to confirm if children are attending emergency departments later than normal during the pandemic and therefore have more severe symptoms by the time they are first seen by healthcare staff.

This study will be performed by the EPISODES study steering group, in collaboration with the European Society of Emergency Medicine and the Research in European Paediatric Emergency Medicine network.

Who can participate?
The collective data of all children presenting to the emergency departments of the participating centres during the period between January 1st, 2018 and May 1st, 2020 will be included in this trial.

What does the study involve?
This study will involve analysis of routinely collected clinical data of all children presenting to emergency departments across Europe over a 2 and half year period. The data will not be identifiable and will be collected on a monthly basis for each individual participating centre during the period spanning the COVID-19 pandemic (beginning February 2020). The historical data (from January 2018 and prior to February 2020) will be collected to serve as a comparison.

What are the possible benefits and risks of participating?
As this study does not involve any change to the care of the children whose data is included and that no individual patient data or identifiable data will be collected, there are not thought to be any risks involved in this study. It is hoped that data will show the impact of the COVID-19 pandemic on the numbers of children presenting to emergency departments across Europe and may, therefore, be used to provide advice on emergency department attendance for children, and to respond rapidly to a potential second wave of the pandemic.

Where is the study run from?
Imperial College London (UK). There are currently 40 confirmed participating sites (1-4 centres per European country) providing data for the study.

When is the study starting and how long is it expected to run for?
From June to December 2021

Who is funding the study?
The study is investigator-initiated and funded.

Who is the main contact?
Dr Ruud Nijman
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
284008

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 284008

Study information

Scientific Title
The epidemiology, severity, and outcomes of children presenting to emergency departments across Europe during the SARS-COV-2 pandemic: the EPISODES study

Acronym
EPISODES

Study objectives
This study aims to describe current patterns of children presenting to paediatric emergency departments across Europe during the SARS-CoV-2 pandemic and compare these with historical data, to understand the timeliness of their presentations in relation to the disease severity, and to monitor for emerging disease entities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2020, UK HRA, Imperial College Research Governance and Integrity Team (Joint Research Compliance Office Office Room 221, Medical School Building, St Mary's Campus, Imperial College London W2 1NY; n.shaikh@imperial.ac.uk; +44 (0)20 7594 9484), ref: 20SM6003

Study design
Retrospective analysis of routinely collected clinical data

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Paediatric emergency department presentation

Interventions
Current interventions as of 01/04/2021:
This study will involve retrospective analysis of routinely collected clinical data of all children presenting to emergency departments across Europe over a 2 and half year period. Aggregated, anonymous data will be entered on a monthly basis for each individual participating centre during the period spanning the COVID-19 pandemic (beginning February 2020). All data will be extracted from electronic health care records by the local clinical teams. Monthly aggregated data will be entered on a validated and secure online platform (RedCap). Aggregated, anonymous data will be presented on a weekly/monthly basis where each week period will start on the first Monday (00:00 am) of that time period, through to the last Sunday (11:59 pm) of that time period. The total time period of interest will be January 1st, 2018 to May 17th, 2020 to allow for the collection of historical data (prior to February 2020) for comparison. Once the data is collected it will be analysed after the end of the period of interest.

A quota sampling design will be used to select from which 1-4 institutions from each participating European countries data will be collected. Every site lead will complete a site-specific survey to inform on hospital-specific factors and local changes to healthcare pathways induced by the SARS-CoV-2 pandemic. No data with personally identifiable data will be collected, nor any data on a patient individual level. Data will be analysed by comparing absolute numbers and percentages of children presenting to emergency departments, the severity of their presenting problems, their working diagnoses, and the patient outcomes, over time during the study period.

We will use historic datasets to calibrate time series auto-regressive integrated moving average (ARIMA) forecasting models, in order to predict the expected number of ED attendances for different conditions using national-level and local data pre- and during the COVID-19 pandemic. We will compare the forecasted trends to the observed data for the same periods of time. Site-specific surveys detailing local health care pathways, and COVID-19 related changes to these pathways, will allow for unique local mediation analysis, and the ARIMA models will be adjusted for local policy interventions on social distancing and other lockdown measures.

An extension of the study period will allow data until May 2021 to be collected.

Previous interventions:
This study will involve retrospective analysis of routinely collected clinical data of all children presenting to emergency departments across Europe over a 2 and half year period. Aggregated, anonymous data will be entered on a monthly basis for each individual participating centre during the period spanning the COVID-19 pandemic (beginning February 2020). All data will be extracted from electronic health care records by the local clinical teams. Monthly aggregated data will be entered on a validated and secure online platform (RedCap). Aggregated, anonymous data will be presented on a weekly basis where each month or each week period will start at the first Monday (00:00 am) of that time period, through to the last Sunday (11:59 pm) of

that time period. The total time period of interest will be January 1st, 2018 to May 1st, 2020 to allow for the collection of historical data (prior to February 2020) for comparison. Once the data is collected it will be analysed after the end of the period of interest.

A quota sampling design will be used to select from which 1-4 institutions from each participating European countries data will be collected. Every site lead will complete a site-specific survey to inform on hospital-specific factors and local changes to healthcare pathways induced by the SARS-CoV-2 pandemic. No data with personally identifiable data will be collected, nor any data on a patient individual level. Data will be analysed by comparing absolute numbers and percentages of children presenting to emergency departments, the severity of their presenting problems, their working diagnoses, and the patient outcomes, over time during the study period.

Intervention Type
Other

Primary outcome(s)
Absolute numbers of children presenting to the paediatric emergency department over the period of interest; for all children and children with different typologies (i.e. working diagnosis, age)

Key secondary outcome(s))
1. The severity of illness of children presenting to the paediatric emergency department over the period of interest as defined by the following criteria: percentage of children with abnormal vital parameters; high triage urgency; a composite outcome of the need for emergency medications, the need for hospital admission for >24 h, the need for PICU admission, and death
2. Change of relative incidence of children with specific diagnoses of interest and the severity of their presentation as a proxy for timeliness of presentations. Calculated from: absolute numbers of children presenting to the paediatric emergency department; the percentage of children with abnormal vital parameters; the number of cases with high triage urgency; a composite outcome of the need for emergency medications, the need for hospital admission for >24 h, the need for PICU admission, and death; over the period of interest and over an equivalent historical time period for comparison

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. All children presenting to the emergency department during the period of interest for unscheduled health care
2. Aged between 0 and 18 years (upper age limit determined by the upper age bracket for children being assessed at the local participating centre)
3. Undergo a formal clinical assessment by advanced nurse practitioner (or equivalent) or clinician in the emergency department
4. All or part of the data of the triaging process (including vital signs), consultation, management (including diagnostics and treatment) and outcomes (including working diagnosis and disposition) routinely documented in the electronic patient record

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Children visiting the emergency department who are then streamed to a primary care service for the initial consultation.
2. Children presenting to the emergency department for scheduled health care or a planned follow-up visit (children who have an unscheduled re-visit to the emergency department within one disease episode are not excluded)

Date of first enrolment
01/01/2018

Date of final enrolment
01/05/2021

Locations

Countries of recruitment
United Kingdom

England

Austria

France

Germany

Hungary

Iceland

Ireland

Italy

Latvia

Lithuania

Malta

Netherlands

Portugal

Slovenia

Spain

Sweden

Türkiye

Study participating centre
Imperial College
London
United Kingdom
W2 1NY

Study participating centre
Medical University Vienna
Paediatric Emergency Outpatient Clinic
Clinical Division of Pediatric Pulmonology, Allergology and Endocrinology
Department of Pediatrics and Adolescent Medicine
Währinger Gürtel 18-20
Vienna
Austria
1090

Study participating centre
Paracelsus Medical University
Paediatric Emergency Department and Paediatric surgery Department
Müllner Hauptstrasse 48
Salzburg
Austria
5020

Study participating centre
Medical University of Graz
Department of General Paediatrics
Auenbruggerplatz 2
Graz

Austria
8036

Study participating centre
Hopital Universitaire Robert-Debre
Paediatric Emergency Department
Bd Sérurier
Paris
France
75019

Study participating centre
Louis Mourier Hospital
Paediatric Emergency Department
178 Rue des Renouillers
Colombes
France
92700

Study participating centre
Armand Trousseau Hospital
Paediatric Emergency Department
26 avenue du Dr-Arnold-Netter
Paris
France
75012

Study participating centre
Jean Verdier Hospital
Paediatric Emergency Department
3 Rue Arthur Groussier
Bondy
France
93140

Study participating centre
Dr. von Hauner Children's Hospital
Paediatric emergency department
Ludwig-Maximilians-University Munich
Lindwurmstraße 4
Munich

Germany
80337

Study participating centre
Heim Pal National Paediatric Institute
Paediatric Emergency Department
Ulloi ut 86
Budapest
Hungary
1089

Study participating centre
Szent Gyorgy University Teaching Hospital of Fejer County
Paediatric Emergency Department
Szekesfehervar
Hungary
8000

Study participating centre
Barnaspitali Hringsins
Hringbraut 101
Reykjavík
Iceland
101

Study participating centre
Children's Health Ireland at Crumlin
Paediatric Emergency Department
Cooley Rd
Crumlin
Dublin
Ireland
D12 N512

Study participating centre
Children's Health Ireland at Temple Street
Paediatric Emergency Department
Temple St
Rotunda

Dublin
Ireland
D01 XD99

Study participating centre
Children's Health Ireland at Tallaght
Paediatric Emergency Department
Tallaght
Dublin
Ireland
D24 NR0A

Study participating centre
University Hospital of Padova
Division of Paediatric Emergency Medicine
Department of Women’s and Children’s Health
Via Giustiniani, 3
Padova
Italy
35128

Study participating centre
ondazione Policlinico Universitario A. Gemelli IRCCS
Department of Woman and Child Health and Public Health
Via della Pineta Sacchetti, 217
Rome
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00168

Study participating centre
Children's Clinical University Hospital
Paediatric emergency department
Riga Stradins University
Vienības gatve 45
Riga
Latvia
-

Study participating centre
Hospital of Lithuanian University of Health Sciences Kauno Klinikos
Eivenių g. 2

Kaunas
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50161

Study participating centre
Mater Dei Hospital
Department of Child and Adolescent Health
Msida
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MSD 2090

Study participating centre
Erasmus MC Sophia
Department General Paediatrics
Dr. Molewaterplein 40
Rotterdam
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Study participating centre
Medisch Centrum Alkmaar, Noordwest Ziekenhuisgroep
Emergency department
Wilhelminalaan 12
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Netherlands
1815 JD

Study participating centre
Hospital Pediátrico, Centro Hospitalar e Universitário de Coimbra
Pediatric Emergency Service
Avenida, R. Dr. Afonso Romão
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Study participating centre
Centro Hospitalar e Universitário de São João
Alameda Prof. Hernâni Monteiro
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Study participating centre
Hospital Dona Estefania
Centro Hospitalar de Lisboa Central
Alameda Santo António dos Capuchos
Lisboa
Portugal
1169-050

Study participating centre
Hospital Prof. Doutor Fernando da Fonseca
Departamento da Criança e do Jovem- Urgencia Pediatrica
IC19
Amadora
Portugal
2720-276

Study participating centre
Centro Hospitalar Tondela-Viseu
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Av. Rei Dom Duarte
Viseu
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3504-509

Study participating centre
University Medical Centre Ljubljana
Univerzitetni Klinični Center
Department of Infectious Diseases
Zaloška cesta 7
Ljubljana
Slovenia
1000

Study participating centre
Cruces University Hospital
Paediatric emergency department
Cruces Plaza, S/N
Barakaldo
Spain
48903

Study participating centre
Hospital Universitario Río Hortega
Paediatric emergency unit
Calle Dulzaina, 2
Valladolid
Spain
47012

Study participating centre
Astrid Lindgrens Children's hospital
Paediatric emergency department
Karolinska University
Anna Steckséns gata 35
Solna
Sweden
171 64

Study participating centre
Sachs' Children and Youth Hospital
Paediatric emergency department
Sjukhusbacken 10
Stockholm
Sweden
118 83

Study participating centre
Faculty of Medicine, Ondokuz Mayıs University
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Department of Pediatrics
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Study participating centre
Leicester Children's Hospital
Paediatric Emergency Medicine Leicester Academic Group
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Leicester Royal Infirmary
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Study participating centre
St. Mary’s Hospital
Department of Paediatric Emergency Medicine
Division of Medicine
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United Kingdom
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Study participating centre
St. Thomas' Hospital
Department of paediatric emergency medicine
Guy's and St. Thomas' NHS Foundation Trust
Westminster Bridge Rd
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Study participating centre
Birmingham Children's Hospital
Paediatric emergency department
Birmingham women's and children's NHS Foundation Trust
Steelhouse Ln
Birmingham
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B4 6NH

Study participating centre
Bristol Royal Hospital for Children
Emergency Department
Upper Maudlin St
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Study participating centre
Alder Hey Children's Hospital
Paediatric emergency department
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from r.nijman@imperial.ac.uk. Requests and study proposals will be reviewed by the steering committee. Any of the data needed for any (approved by the steering committee) proposed analysis will be shared. These data will not contain patient individual data and are only available in aggregated and fully anonymised form. UK HRA approval was obtained; no patient informed consent was needed. Data will become available after acceptance of first publication of the main study results. Data will be available for 10 years after study closure.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/08/2022	30/08/2022	Yes	No
Results article	paediatric emergency visits in Sweden	22/06/2021	03/09/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	13/05/2020	03/09/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes