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Coronavirus infection in immunosuppressed children

Submission date	Recruitment status	[_] Prospectively registered
13/07/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/07/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/03/2022	Infections and Infestations	

Plain English summary of protocol

Background and study aims
This study is designed to allow families of immunosuppressed children and young people to self-record their experiences of COVID-19 and other viral respiratory illnesses during the COVID-19 epidemic.

Who can participate?
Parents of immunosuppressed patients and young people aged 16-17 years who are immunosuppressed

What does the study involve?
Participants will be provided with online information and asked to fill in online questionnaires at baseline and weekly thereafter. Information collected will include immune-system affecting medication, symptoms, contact with health care providers, test results and impact on daily activities. Data will be collected and analysed weekly to be able to monitor any potential risk factors for severe disease.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Southampton General Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2020 to March 2022 (updated 02/03/2021, previously: June 2021)

Who is funding the study?
British Paediatric Allergy, Immunity and Infection Group

Who is the main contact?
Dr Hans De Graaf, hans.degraaf@uhs.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04382508

Central Portfolio Management System (CPMS)
45332

Study information

Scientific Title
Coronavirus infection in primary or secondary immunosuppressed children

Study objectives
Children vulnerable to infections are more frequently and more severely affected by SARS-CoV-2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2020, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; no telephone number provided; leedswest.rec@hra.nhs.uk), ref: 20/YH/0110

Primary study design
Observational

Study design
Observational qualitative study

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Eligible patients will be identified by the team responsible for their clinical care. Patients and/or parents will be contacted NHS clinical methods with a weblink directing them to the study website. This website will provide information about the study, an email address to ask questions if required and links to current NHS, Dept of Health and Social Care, and Public Health England COVID-19 advice.

If the patient and/or parent are willing to participate they will complete an online consent form. Data of enrolled patients will be checked with their health records to confirm eligibility.

Data will be collected via online questionnaires. The first questionnaire will include information about the patient, their disease and the medication they are using. Following this they will be sent a link each week inviting them to fill in an online questionnaire. These weekly questionnaires will monitor possible symptoms of COVID-19 (and other current respiratory tract illnesses), results of COVID-19 testing, contact with people diagnosed with COVID-19, general practitioner (GP) or health care attendance, hospital admission, incidences of self-isolation, the stopping or postponing of immunosuppressive drugs, effects on daily life, possible flare of any auto-immune disease (in relevant patients) and parental anxiety. They will also be provided with up to date information and advice and an email address for any further questions.

It will be clear to families that they should continue to link to and liaise with their paediatric speciality clinical teams as per normal routine and emergency care and not through the study helpline.

All participants will be provided with a lay summary of results when the study is completed.

Intervention Type
Other

Primary outcome(s)
COVID-19 infection in children/adults assessed by online questionnaire as frequency of: cough, fever, diarrhoea, shortness of breath, sore throat, blocked nose, red eyes, headache, joint pain, muscle pain, fatigue, chills, nausea, vomiting, over a year

Key secondary outcome(s)
Over the 1 year period:
1. Number of children/adults tested positive for COVID-19 measured using patient records
2. Patient/parent reported positive tests for COVID-19 measured using the online questionnaire
3. Number of children/adults admitted in hospital because of COVID-19 measured using patient records
4. Patient/parent reported admissions in hospital because of COVID-19 measured using the online questionnaire
5. To assess the impact of COVID-19 infection on the daily activities of immunosuppressed adults and children measured using patient records
6. Patient/parent reported effect of COVID-19 on daily activities measured using the online questionnaire

Completion date
17/03/2022

Eligibility

Key inclusion criteria
1. Parent of immunosuppressed patient aged <16 years or immunosuppressed patient aged 16-17 years
2. Family able to complete the questionnaire which will be in English (due to current resources available translation will not be possible)
3. Reliable access to the internet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
2900

Key exclusion criteria
Unable to understand English

Date of first enrolment
17/03/2020

Date of final enrolment
15/03/2021

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Southampton General Hospital
University of Southampton and University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Addenbrookes Hosital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Alder Hey Children's Hosptial
Eaton Road
Liverpool
United Kingdom
L12 2AP

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel Road

London
United Kingdom
E1 1FR

Study participating centre
Birmingham Women's and Children's Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG

Study participating centre
Bradford Royal Infirmary
Bradford Teaching Hospitals NHS Foundation Trust
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Bristol Royal Hosptial for Children
University Hospitals Bristol and Weston NHS Foundation Trust
Upper Mauldin Street
Bristol
United Kingdom
BS2 8BJ

Study participating centre
University Hospital of Wales
Cardiff and Vale University Health Board
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Dumfries & Galloway Royal Infirmary
A75
Cargenbridge

Dumfries
United Kingdom
DG2 8RX

Study participating centre
Burnley General Teaching Hospital
East Lancashire Hospitals NHS Trust
Casterton Ave
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Great North Children's Hospital
Victoria Wing
Royal Victoria Infirmary
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Guys & St Thomas NHS Foundation Trust
20 St Thomas St
London
United Kingdom
SE1 9RS

Study participating centre
Hull University Teaching Hospital
Anlaby Rd
Hull
United Kingdom
HU3 2JZ

Study participating centre
St Mary's Hospital
Imperial College Healthcare Trust
The Bays
S Wharf Rd
Paddington
London
United Kingdom
W2 1NY

Study participating centre
James Paget University Hospitals NHS Foundation Trust
Lowestoft Road
Gorleston-on-Sea
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Kent Community Health NHS Foundation Trust
The Oast House
Hermitage Ct
Maidstone
United Kingdom
ME16 9NT

Study participating centre
Chorley and South Ribble Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Preston Road
Chorley
United Kingdom
PR7 1PP

Study participating centre
Leeds Children's Hospital
Leeds General Infirmary
Great George St
Leeds
United Kingdom
LS1 3EX

Study participating centre
Lewisham Hospital
Lewisham High St
London
United Kingdom
SE13 6LH

Study participating centre
Crosshouse Hospital
NHS Ayrshire & Arran
Kilmarnock Rd
Crosshouse
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
NHS Forth Valley
Castle Business Park
Stirling
United Kingdom
FK9 4SW

Study participating centre
NHS Lanarkshire
14 Beckford St
Hamilton
United Kingdom
ML3 0TA

Study participating centre
Ninewells Hospital
NHS Tayside
230 Clepington Rd
Dundee
United Kingdom
DD2 1GZ

Study participating centre

Norfolk and Norwich University Hospital
Colney Ln
Norwich
United Kingdom
NR4 7UY

Study participating centre
Royal Oldham Hospital
Northern Care Alliance NHS Group
Rochdale Rd
Oldham
United Kingdom
OL1 2JH

Study participating centre
Nottingham Children's Hospital
Queen's Medical Centre
Derby Rd
Nottingham
United Kingdom
NG7 2UH

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals NHS Trust
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Poole Hospital
Poole Hospital NHS Trust
Longfleet Rd
Poole
United Kingdom
BH15 2JB

Study participating centre

Princess Alexandra Hospital for Sick Children
Royal Alexandra Children's Hospital
Royal Sussex County Hospital
North Dr
Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal Hospital for Children, Glasgow
Queen Elizabeth University Hospital
1345 Govan Rd
Glasgow
United Kingdom
G51 4TF

Study participating centre
Royal Hospital for Sick Children, Edinburgh
9 Sciennes Rd
Edinburgh
United Kingdom
EH9 1LF

Study participating centre
Royal Manchester Children's Hospital
Oxford Rd
Manchester
United Kingdom
M13 9WL

Study participating centre
The Royal Marsden Hospital
Royal Marsden NHS Foundation Trust
Downs Rd
Sutton
United Kingdom
SM2 5PT

Study participating centre
Royal Sussex County Hospital
Eastern Rd

Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Salisbury District Hospital
Salisbury NHS Foundation Trust
Odstock Rd
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Sheffield Children's NHS Foundation Trust
Clarkson St
Broomhall
Sheffield
United Kingdom
S10 2TH

Study participating centre
Shrewsbury & Telford Hospital
Mytton Oak Rd
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
St George's University Hospital
St George's University Hospital NHS Foundation Trust
Blackshaw Rd
London
United Kingdom
SW17 0QT

Study participating centre
Swansea Bay University Local Health Board
Port Talbot
United Kingdom
SA12 7BR

Study participating centre
University College Hospital
University College London Hospitals NHS FT
235 Euston Rd
Bloomsbury
London
United Kingdom
NW1 2BU

Study participating centre
University Hospitals Coventry and Warwickshire National Health Service Trust
Clifford Bridge Rd
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospitals of North Midlands NHS Trust
Weston Rd
Stafford
United Kingdom
ST16 3SA

Study participating centre
Walsall Manor Hospital
Walsall Healthcare NHS Trust
Moat Rd
Walsall
United Kingdom
WS2 9PS

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Research council

Funder Name
British Paediatric Allergy, Immunity and Infection Group

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/03/2021	11/03/2022	Yes	No
HRA research summary			26/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes