Coronavirus infection in immunosuppressed children

Submission date 13/07/2020	Recruitment status No longer recruiting	Prospectively registered		
		∐ Protocol		
Registration date 14/07/2020	Overall study status Completed	Statistical analysis plan		
		[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

Contact name

Dr Hans De Graaf

Contact details

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Type(s)

Scientific

Contact name

Prof Saul Faust

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT04382508

Protocol serial number

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

Study design

Observational qualitative study

Primary study design

Observational

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

Kev 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

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 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes