ISRCTN99910769 https://doi.org/10.1186/ISRCTN99910769

The impact of COVID-19 infection in newborns or in pregnancy on children's development at 18-24 months

Submission date
28/04/2022

Recruitment status
No longer recruiting

Registration date
06/06/2022

Overall study status
Completed

Last Edited
17/01/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims:
Two large ongoing studies, the UK Obstetric Surveillance System (UKOSS) and the British Paediatric Surveillance Unit (BPSU), identified 3000 pregnant women and 100 newborn babies who were hospitalized with the Coronavirus (SARS-CoV-2 or COVID-19) infection so far. Most of these pregnant women gave birth at term (at 37 weeks of gestation or more) and most of the newborn babies who had Coronavirus infection were also born at term. Almost all of these babies were well or were only mildly affected by the virus shortly after birth. Recent research shows that Coronavirus infection in children and adults may affect the brain. Since the development of term-born babies is not routinely checked by health professionals, we will not know whether Coronavirus infection during pregnancy or shortly after birth will affect their development as they grow. This study therefore aims to check the development of babies exposed to Coronavirus infection and compare it with the development of babies who did not have Coronavirus infection to find out if there are any lasting effects.

Who can participate?
Three groups of potential participants will be invited to take part:
1. Infants who had COVID-19 within 28 days after birth (neonatal exposure group)
2. Infants born to mothers who had COVID-19 during pregnancy (antenatal exposure group)
3. Infants who did not have COVID-19 in the first 28 days after birth, and whose mothers who did not have COVID-19 during pregnancy (comparison group)

What does the study involve?
Hospitals across the UK will send study invitation letters and information packs to mothers of infants who are eligible to take part in this study. These study information packs will include paper copies of the consent form and study entry questionnaire. Links to online versions of these forms will also be provided in the information pack. Mothers of eligible infants who would like to take part in the study will be asked to return the completed forms to the University of Bristol using the prepaid addressed return envelope provided in the information pack, or to complete the online versions of these forms if preferred. The study entry questionnaire will ask mothers to provide a contact address (email or postal) or phone number. These details will be

used to contact mothers when their child is 18-24 months of age to invite them to complete questionnaires about how their child is developing. These development questionnaires can be filled in online, or if preferred, paper versions of the questionnaire will be posted along with a prepaid addressed return envelope. If translation to a different language is needed, questionnaires can be completed over the phone using translation services. These questionnaires will include the Ages and Stages Questionnaire (ASQ) which is a validated questionnaire used by professionals to monitor a child's developmental progress. The researchers will also ask some information about the child's medical history and health care usage.

What are the possible benefits and risks of participating?
This study will help the researchers to understand whether contracting Coronavirus during pregnancy may affect how a baby develops later in life. Although there is no direct benefit to participating, this information will help to organise support for families and children if a woman contracts Coronavirus during pregnancy and will help the NHS develop guidance and support for pregnant women. The researchers will also inform the parents of the children taking part in the study on the results of their child's development, as assessed from the questionnaire they complete. They also plan to follow the development of children recruited into the study as they grow up. There are no disadvantages in taking part in the study. Completing the questionnaires will require up to 30 minutes.

Where is the study run from?
The study is run by the research team who are based at the University of Bristol, the National Perinatal Epidemiology Unit at the University of Oxford, the Department of Health Sciences at the University of Leicester, and Imperial College, London (UK)

When is the study starting and how long is it expected to run for?
December 2020 to December 2023

Who is funding the study?
Action Medical Research (UK)

Who is the main contact?
sinepost-study@bristol.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
294183

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 48937, IRAS 294183

Study information

Scientific Title
SARS-CoV-2 Infection in NEonates or in Pregnancy: Outcomes at EighTeen months (SINEPOST)

Acronym
SINEPOST

Study objectives
Antenatal and/or neonatal exposure to SARS-CoV-2 impacts infants' development at 18-24 months of age.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 04/05/2021, London - Westminster Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048310; westminster.rec@hra.nhs.uk), ref: 21/PR/0431

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Other

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

Interventions
SINEPOST is a population-based cohort study that is linked to the national surveillance studies of pregnant women (UK Obstetric Surveillance System) and newborn babies (British Paediatric Surveillance Unit, BPSU) hospitalized with confirmed Coronavirus infection. The SINEPOST study will determine the impact of antenatal or neonatal exposure to the Coronavirus infection on the developmental outcomes at 18 months of age.

The study will apply for the Urgent Public Health Research Status and will operate through the Reproductive Health and Childbirth and Children's Clinical Research Network (CRN). The study will begin at the Bristol hospitals, Imperial College and Nottingham. Each site will have a local principal investigator who will provide the clinical leadership. Once the study commences, the study coordinator based at the National Perinatal Epidemiology Unit in the University of Oxford will actively approach the Clinical Research Networks around the UK for inclusion in the SINEPOST study.

The Study Coordinator will send the study packs to the site PIs/CRN research nurses either through email or post. The study packs will contain a letter inviting the women or parent to participate in the study from respective hospital trusts, parent information sheet, consent form and a study entry questionnaire with a unique SINEPOST ID. The participant information sheet, consent form and the study entry questionnaire for the antenatal exposure and the neonatal exposure cohort will contain the UKOSS and the BPSU study ID in addition to the SINEPOST ID.

Antenatal exposure and comparator cohort recruitment
The CRN research nurses will find the personal information of women who had the Coronavirus infection during pregnancy from locally held information using the UKOSS ID. They will add the personal information and address to the study pack and send the study pack to women eligible for the antenatal exposure cohort. The CRN research nurses will choose one woman who had term singleton babies but did not have Coronavirus infection during pregnancy on either side of the woman who had the Coronavirus infection during pregnancy. The CRN research nurses will add the personal information and address to the study pack. The study pack will be sent to the potential participants.

Neonatal exposure cohort recruitment
The CRN research nurses will identify the personal information of children who had SRAS-CoV-2

infection shortly after birth using the BPSU study ID, NHS number or date of birth sent by the study coordinator. The CRN research nurses will add the personal information and address to the study pack and send the study pack to the parents of all the eligible infants.

The parent information sheet will explain the study to the parents. Parents will be able to obtain additional information about the study before consenting by contacting the study team through email or dedicated mobile number via text or call to directly communicate with the study team or leave a voice mail for the study team to return the call or will be able to write to the study team. Parents will be able to complete the consent form and the study entry questionnaire online using a computer or phone or return a completed paper form using the stamped addressed envelope. The consent form will ask for the email address, mobile number and home address in order to send the development questionnaire to the participants. The consent form will ask parents to consent to this study, and will also ask parents' permission to store their contact details to enable us to contact them in the future for later follow-up studies and for obtaining information on their child's educational attainment and health care usage information through linking of their child's personal information with the Department of Education and NHS Digital. Parents will be free to choose which of these activities (none, one or more, all) to consent as appropriate. The study entry questionnaire will ask for demographic characteristics, need for translation services, their preferred mode for completing the developmental screening questionnaires at 18 months (online or over phone or paper version), any medical problems that might impact their child's development and details of the Coronavirus infection.

Key study research team will comprise of a study researcher at Bristol and a study coordinator at NPEU, Oxford. Every week, the study researcher at Bristol will inform the study coordinator based at NPEU, Oxford, the SINEPSOT IDs of the participants who have consented to participate in the study. For the participants who have not returned the consent forms within three weeks, the study coordinator will liaise with the local PI /CRN research nurses. The study coordinator will send another study pack and a reminder letter to resend to the potential participants of the antenatal and neonatal exposure cohort.

Once parents consent for their child to participate in the study, the study researcher at Bristol will enroll the parents' email address and mobile number onto the REDCap, which is a secure web-based application. The developmental screening questionnaires can be completed online or over phone or on a paper version that can be returned using the stamped addressed envelope. When the children are 17 months of age, REDCap will send the weblink for the developmental screening questionnaires through email or as a text message. If the parents do not complete the questionnaires in 2 weeks, REDCap will send an automatic reminder to the parents. The study researcher will complete the questionnaires over phone for those parents who had chosen this option. For the parents who need translation, the study researcher will use the Language Line service when the parents are called over phone to complete the questionnaire. If the questionnaires are not completed after 2 weeks following the reminder, the study researcher will contact the parents via telephone. Depending on parents' preference, the questionnaire could either be completed over phone or online at this juncture.

The researchers will use the Ages and Stages Questionnaire-version 3 (ASQ-3) and Ages and Stages Questionnaire Social-Emotional-version 2 (ASQ-SE-2) to capture the development of children in communication, gross motor, fine motor, problem solving, personal social and social-emotional skills. These questionnaires are widely used in clinical settings and research to check the development of children of this age. These questionnaires can be completed by parents. The researchers will score the questionnaires. The scores will identify whether the child's development is within the average range for his/her age or whether they are at-risk for developmental delay. The researchers will send the results of the questionnaire to the parents.

For those children whose score indicates that they may be at-risk of developmental delay, the researchers will suggest parents contact their child's health visitor or their general practitioner for further support and assessment.

Sample size
The researchers estimated the sample size based on the following factors:
1. The anticipated deficit in developmental test score associated with exposure to the Coronavirus or Coronavirus associated inflammation is likely to be similar to that seen in infants who were exposed to mild birth asphyxia.
2. Based on previous studies, the anticipated response rate for the invitation to participate in the SINEPOST study using the UKOSS platform is likely to be 20%. However, given the high profile of this research topic and the willingness of the healthcare providers and the public to contribute to research about the Coronavirus, the response rates may be higher.
3. The researchers will need to increase our target sample size to robustly determine the longer-term impact of exposure to the Coronavirus on development at school-age to account for attrition to follow up after 18 months of age.

Considering all these factors, the researchers have estimated that they will need 200 children in the antenatal exposure and the comparator cohort. Given the neonatal exposure cohort currently has 100 eligible children, which is likely to increase with the second wave, the researchers will invite all the eligible children to participate in the SINEPOST study aiming to recruit up to 120 children. To achieve this sample size, they will invite around 1000 women in the antenatal exposure and the comparator cohort. The researchers will assess the recruitment rate 4-6 months into the study. If they are not achieving the expected recruitment, they will increase the number of women who are invited for the study. For example, to increase the recruitment for the comparator cohort, the researchers will invite four women for every index child in the antenatal exposure cohort (two on either side of birth of the index infant).

Timetable
The researchers will commence the study in May 2021 after obtaining ethics and HRA approval and recruiting the study personnel. The study set up including setting the data collection will complete by April 2021. Recruitment will commence from May 2021 and finish by April 2022. The developmental assessment using parental ASQ questionnaires at 18 months of age will last between August 2021 and July 2022. The researchers will undertake the data analysis, report writing and dissemination from July 2022 to October 2022. The study management committee will meet weekly during the initial stages of the study and will then meet monthly in the later stages to conduct the study.

Intervention Type
Other

Primary outcome(s)
Child development measured using the mean Ages and Stages Questionnaire (ASQ-3) total score at 21-24 months old

Key secondary outcome(s))
1. Proportion with one or more ASQ-3 domain scores below the established cut-offs which identify possible developmental delay, measured at 21-24 months old
2. Proportion of ASQ-3 domain scores below the established cut-offs which identify possible developmental delay, measured at 21-24 months old
3. Child development measured using the Mean Ages and Stages Questionnaire: Social-

Emotional (ASQ-SE-2) total score and the proportion of ASQ-SE-2 total scores above the established cut-offs which identify possible developmental delay, measured at 21-24 months old
4. Respiratory symptoms measured using the mean Liverpool Respiratory Symptoms Questionnaire (LRSQ) total score at 21-24 months old
5. Frequency of health care usage measured using a non-validated questionnaire at 21-24 months old

Completion date
17/12/2023

Eligibility

Key inclusion criteria
For the coronavirus-exposed cohort, any term (≥37 weeks gestation) baby:
1. Born to women who had confirmed coronavirus infection between 14 and 36 weeks of pregnancy will form the antenatal exposure cohort
OR
2. Who had confirmed coronavirus infection within 28 days of birth will form the neonatal exposure cohort

The comparator cohort will include any term baby:
1. Who did not have coronavirus infection within 28 days of birth AND
2. Born to women who did not have coronavirus infection during pregnancy in the same period as the antenatal exposure cohort

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Children born prematurely at less than 37 weeks gestation
2. Children with a major congenital anomaly
3. Children born following multiple pregnancies

Date of first enrolment
16/11/2021

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
United Kingdom

England

Wales

Guernsey

Study participating centre
Aneurin Bevan University Health Board
Lodge Road
Caerleon
Newport
United Kingdom
NP18 3XQ

Study participating centre
The Grange University Hospital
Caerleon Road
Cwmbran
United Kingdom
NP44 8YN

Study participating centre
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Barnsley Hospitals
118 Gawber Road
Barnsley
United Kingdom
S75 2PS

Study participating centre
Newham General Hospital
Glen Road

London
United Kingdom
E13 8SL

Study participating centre
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Whipps Cross Hospital
Whipps Cross Road
London
United Kingdom
E11 1NR

Study participating centre
Bedford Hospital
Icash Bedford Hospital
Kempston Road
Bedford
United Kingdom
MK42 9DJ

Study participating centre
Luton & Dunstable Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Birmingham Womens Hospital
Metchley Park Road
Birmingham
United Kingdom
B15 2TG

Study participating centre
Bolton Royal Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
Rosie Hospital
Robinson Way
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Chelsea & Westminster Hospital
369 Fulham Road
London

United Kingdom
SW10 9NH

Study participating centre
West Middlesex University Hospital
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Croydon University Hospital
London Road
Croydon
United Kingdom
CR7 7YE

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Bassetlaw District General Hospital
Kilton Hill
Worksop
United Kingdom
S81 0BD

Study participating centre
Dorset County Hospital
Dorset County Hospital
Princes Street
Dorchester
United Kingdom
DT1 1TS

Study participating centre
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Lancashire Women and Newborn Centre
Burnley General Hospital
Casterton Ave
Burnley
United Kingdom
BB10 2PQ

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Epsom General Hospital
Dorking Road
Epsom
United Kingdom
KT18 7EG

Study participating centre
George Eliot Hospital
College Street
Nuneaton

United Kingdom
CV10 7DJ

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
The Great Western Hospital
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Evelina Children's Hospital
Lambeth Palace Road
London
United Kingdom
SE1 7EH

Study participating centre
Homerton University Hospital
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre

St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Queen Charlotte's and Chelsea Hospital
Du Cane Rd
London
United Kingdom
W12 0HS

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre
Princess Royal University Hospital
Farnborough Common
Orpington
United Kingdom
BR6 8ND

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Queen Elizabeth Hospital
Woolwich Stadium Road
Woolwich

London
United Kingdom
SE18 4QH

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

Study participating centre
Liverpool Womens Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
Tunbridge Wells
United Kingdom
TN2 4QJ

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
St Marys Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Pinderfields General Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Princess Royal Maternity Hospital
16 Alexandra Parade
Glasgow
United Kingdom
G31 2ER

Study participating centre
Royal Hospital for Sick Children (Glasgow)
1345 Govan Road

Glasgow
United Kingdom
G51 4TF

Study participating centre
Royal Alexandra Hospital
Corsebar Road
Paisley
United Kingdom
PA2 9PN

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Princess Elizabeth Hospital, Le Vanquiedor
Rue Mignot
St Martins
Guernsey
GY4 6UU

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Hinchingbrooke Hospital
Hinchingbrooke Park
Huntingdon
United Kingdom
PE29 6NT

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Oldham Care Organisation - Nmp
Butler Green House
Wallis Street
Chadderton
Oldham
United Kingdom
OL9 8NG

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Queens Medical Centre
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Royal Free Hospital
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Barnet Hospital
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Study participating centre

Royal Surrey County Hospital Guildford
Egerton Road
Guildford
United Kingdom
GU2 7XX

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

Study participating centre
New Cross Hospital Royal Wolverhampton
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Birmingham City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
Sheffield Childrens Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Jessops Wing
Royal Hallamshire Hospital
Glossop Road

Sheffield
United Kingdom
S10 2JF

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
St Georges Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Whiston Hospital
St. Helens & Knowsley Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Stepping Hill Hospital
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Hillingdon Hospital
Hillingdon Hospital
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
St James's University Hospital NHS Trust
St James's University Hospital
Gledow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Study participating centre

University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Princess Anne Hospital
Coxford Road
Southampton
United Kingdom
SO16 5YA

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5ST

Study participating centre
Good Hope Hospital
Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

Study participating centre
St Michaels Hospital
St. Michaels Hospital

Hayle
United Kingdom
TR27 4JA

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2DX

Study participating centre
St Marys Maternity Unit
Poole Hospital
St Mary's Rd
Poole
United Kingdom
BH15 2BH

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
St Richards Hospital Laboratory
St. Richards Hospital
Spitalfield Lane
Chichester
United Kingdom
PO19 6SE

Study participating centre
Royal Alexandra Children's Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Warrington Hospital (site)
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
Watford General Hospital
60 Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre
The Whittington Hospital
Highgate Hill
London
United Kingdom
N19 5NF

Study participating centre

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

Study participating centre
The Worcestershire Royal Hospital
Newtown Road
Worcester
United Kingdom
WR5 1ZL

Study participating centre
Scarborough General Hospital (alliance Medical Scanning)
Scarborough Hospital
Woodlands Drive
Scarborough
United Kingdom
YO12 6QL

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Charity

Funder Name
Action Medical Research; Grant Codes: GN2905

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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?
Protocol article		01/09/2022	17/01/2023	Yes	No
HRA research summary			28/06/2023	No	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