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The babies' longitudinal outcomes, 'omics, and milestones study

Submission date
23/06/2025

Recruitment status
Recruiting

Registration date
01/07/2025

Overall study status
Ongoing

Last Edited
26/01/2026

Condition category
Neonatal Diseases

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

Plain English summary of protocol
Background and study aims
We know that some babies who need neonatal care can face challenges in their later health, learning, and development. We aim to understand which babies might benefit from extra help at an early age. BLOOMS is a new research project designed to understand how we can better support children who need neonatal care as they grow.
The aims of BLOOMS are to:
1. Improve how we use information from newborn genetics alongside other information to make earlier and more accurate diagnoses
2. Discover early warning signs that could help doctors and teachers provide support before problems become serious in childhood
3. Understand the causes of poor health and developmental outcomes, so we can work to improve those outcomes in young children

Who can participate?
We are inviting families with a baby who is currently admitted to a specialist NICU in Cambridge, Luton, or Norwich to take part. The baby has to be admitted to the NICU for 48 hours or more, and has to have an adult with parental responsibility available to sign consent.

What does the study involve?
Parents will be asked to read and sign a consent form for themselves and their baby
Parents will be asked to provide their and their baby's name, date of birth, NHS number, and contact details and allow us to store them.
Parents will be asked to complete electronic questionnaires to provide some more information about themselves and their family, such as medical history, schooling, work, etc.
Soon after the consent form is signed, the clinical team will obtain a small blood sample from the baby. A member of the research team will also arrange for a blood sample to be collected from each parent who is happy to take part.
Before the baby is discharged from the NICU, the clinical team will obtain another small blood sample from them as well as a poo sample from their nappy.
After the baby is discharged from the NICU, families will be contacted when the baby is 9 months old, then 2, 4, and 5 years old for developmental assessments and parent questionnaires that can be done easily at home.

Families will be invited to bring the baby to Cambridge when they are 3 years old for a visit that includes a full developmental assessment, measurements of height/weight and an EEG (a painless test that records the brain's electrical activity). At the same visit another small blood sample and a stool sample from the baby will be arranged.
We will ask for consent to have access to the baby's health records and to access information collected about them through health and education records until they turn 16 years old.
We will also ask to access the health records of parents who were pregnant, from before birth until 1 year after birth.
Families' active involvement in the study is for 5 years. Information collected about babies through health and education records will be accessed by the study until they turn 16 years old.

What are the possible benefits and risks of participating?
There may be extra information arising from the study that could help the clinical team looking after your child. Your child will be essential to the study's success and will receive annual birthday presents from the study team.
Taking part in BLOOMS is designed to help other families whose babies need neonatal care in the future, and to find ways of supporting children in the future.
There are no risks to the baby or to parents. Blood sampling can be uncomfortable; for young children samples are always taken by fully trained staff who will make the process as simple as possible.

Where is the study run from?
The study is being jointly run from the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2025 to January 2042

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Prof. Catherine Aiken, cema2@cam.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
344546

ClinicalTrials.gov (NCT)
Nil known

Funding body reference
Wellcome Trust 312471/Z/24/Z

Study information

Scientific Title
Prediction of NICU babies' longitudinal health, neurodevelopmental, and educational outcomes from a multiomics data study (BLOOMS)

Acronym
BLOOMS

Study objectives
The rationale behind this study is to determine if we can use multiomics data from NICU babies to predict the early life antecedents of poor health and neurodevelopmental outcomes,

including school readiness. Discovering early warning signs (biomarkers) could help doctors and teachers provide support before problems become serious, and understanding the root causes of poor health and developmental outcomes can enable us to work to prevent them.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/08/2025, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 25/NS/0084

Study design
Multicentre observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Babies currently admitted to the tertiary NICU for at least 48 hours

Interventions
For this observational study, families will be asked to consent to three study elements: (i) sampling of blood/stool for generation of multi-omic data, (ii) remote and in-person developmental assessments up to age 5, and (iii) permission for ongoing remote data linkage to routinely-collected sources until the child turns 16 years old. Families will actively participate in the study for up to 5 years, which will include two in-person study contacts: at recruitment in the NICU and when the child is 3 years old. They will also be asked to provide information and participate in remote study contacts at annual intermediate time-points.

At all visits questionnaires will be used to collect a variety of types of information about the family (e.g. demographic information, socio-economic information, social support, parenting styles), family health and well-being (e.g. Edinburgh post-natal depression scores), and childhood development (e.g. CREDI or equivalent at various ages), including measures of language development and socio-emotional well-being.

At the initial visit in the NICU, parental blood sampling will be undertaken by a member of the research team and the baby will have their initial blood sample taken by a member of the clinical team. A second blood sample will be taken from the baby by the clinical team at the next suitable opportunity. A stool sample will be obtained by the clinical team during routine care for the baby. When the baby is 9 months old, then 2, 4, and 5 years old, the family will be contacted to arrange developmental assessments and parent questionnaires that can be done easily at home.

When the baby is 9 months old, electronic questionnaire links will be sent via the participant’s preferred method.

At 2 years following birth, electronic questionnaire links will be sent via the participant's preferred method. The study team will phone the parents to talk through arrangements for home recording of a parent and child playing together. Parents will also be sent a link to an online survey, which will include updates on key demographic and family information recorded at 9 months, as well as new parent-reported developmental measures, suitable for this age group (e.g. language development, including vocabulary, cognition development, motor development, social and emotional development and behavioural problems, and early autism traits). Parents will also be asked to complete questionnaires regarding their parental style and activities to support the child's learning and development in the home, assessments of the child' s height and weight, as well as early childhood education and care provision.

At an in-person developmental assessment at 3 years old, children will undergo standardised and validated developmental assessments. An EEG will be recorded in the resting state, with visual and audio stimuli (social and non-social), executive function and language tasks. A blood sample will be taken from the child by a suitably trained member of the research team with the assistance of other support team members and parents as required according to the study SOP. Parents will also be given a stool sampling kit at the in-person visit. Clear instructions will be provided by the study team on how to obtain a sample and post the kit back to the research team.

At 4 and 5 years old, electronic questionnaire links will be sent via the preferred method of communication.

Relevant medical data will be extracted from the locally held medical records of the baby and mother at birth and 9 months of age.

Health and growth outcomes between birth and 16 years will be assessed via linkage to routinely collected data sources, including NHS (e.g. HES, primary data) and the national childhood measurement programme. Educational attainment aged 5 – 16 years will be assessed via linkage to the National Pupil database.

Intervention Type
Other

Primary outcome(s)
To discover links between biomarkers, genome, and long-term outcomes that can provide insight into fundamental developmental mechanisms, early origins of disease, and learning disability, using the following measures:
1. Whole genome sequences (WGS) from the baby and parents from blood samples obtained at the time of consent to NICU
2. Other multi-omic data from baby and parents, e.g. proteome, methylome, microbiome from samples obtained at time of consent to NICU
3. Demographic, socio-economic, family health and circumstances, other relevant life-style information measured using electronic questionnaires administered at time of consent in NICU, 9 months and 2, 3, 4, and 5 years
4. Developmental skills, abilities, and wellbeing measured via in-person and remote developmental assessments and questionnaires between birth and 5 years
5. Data extracted from the locally held medical records of the baby and mother at birth and 9 months of age

6. Health and growth outcomes measured via linkage to routinely-collected data sources, including NHS (e.g. HES, primary care data) and national childhood measurement programme between birth and 16 years

Key secondary outcome(s))
To stratify the risks of adverse educational outcomes using early markers:
1. Educational attainment is measured via linkage to the National Pupil database at age 5 to 16 years

Completion date
01/01/2042

Eligibility

Key inclusion criteria
Inclusion criteria for babies:
1. Admitted to a tertiary-level neonatal unit (NICU) in the East of England
2. Admitted to a tertiary level NICU for ≥48 hours
3. Has an adult with parental responsibility available to sign consent

Parents of babies will also be included in the study if they:
1. Have parental responsibility for the baby
2. Are aged 18 years or above
3. Are willing and able to give informed consent in English for participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
1 days

Upper age limit
28 days

Sex
All

Total final enrolment
0

Key exclusion criteria
1. There is no adult with parental responsibility who can consent in English
2. Does not meet inclusion criteria

Date of first enrolment
01/01/2026

Date of final enrolment
01/01/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
England
NR4 7UY

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
England
LU4 0DZ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

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 anonymised datasets generated during and/or analysed during the current study will be available upon request at the discretion of the chief investigator, Professor Catherine Aiken, cema2@cam.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	31/07/2025	26/01/2026	No	No