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Long-term assessment of developmental outcomes of newborn babies with sepsis

Submission date
06/05/2026

Recruitment status
Recruiting

Registration date
14/05/2026

Overall study status
Ongoing

Last Edited
08/05/2026

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Blood infection in the first month of life (known as neonatal sepsis) is among the major causes of illness and death in newborn babies. It is also known that blood infections in newborn babies may affect a child's development as they grow. This study looks at how children who recovered from a blood infection as newborns grow and develop over time.

Who can participate?
Infants aged one day to one month with neonatal sepsis enrolled on the NeoSep1 trial (https://www.isrctn.com/ISRCTN48721236) and/or SNIP-AFRICA surveillance study at a participating NeoSep LTFU1 site.

What does the study involve?
The study will take place in Ghana, South Africa, Tanzania and Uganda. A tool called the Global Scales for Early Development (GSED)-Short Form, developed by the World Health Organization will be used to assess the development of the children in the study. The GSED tool assesses what a child can do, such as moving, how well they see and hear, and how they play and interact with others.

What are the possible benefits and risks of participating?
Benefits of taking part in the study
There are no direct benefits to being part of the study. There will be no payment for taking part in the study, but parents/guardians may be able to claim some travel expenses from the local study team. The findings may help improve treatment and care for babies with infections in the future. We hope to help medical teams provide better care for babies with sepsis and to support parents in understanding the long-term outcomes of neonatal sepsis.

Risks of participating in the study.
Being part of the study involves no physical risks for the parent/guardian or the baby. Any child who cannot do tasks they should be able to do at their age will be referred for further assessment through routine care available at the participating health facility.

Where is the study run from?
City St. George's University of London, UK.

When is the study starting and how long is it expected to run for?
June 2026 to May 2029.

Who is funding the study?
Gates Foundation, USA.

Who is the main contact?
Charlotte Sanders, Senior Research Project Manager csanders@sgul.ac.uk

Contact information

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Additional identifiers

Study information

Scientific Title
Long-term neurodevelopmental outcomes of infants following neonatal sepsis: a multicentre prospective cohort study

Acronym
NeoSep LTFU1

Study objectives
To estimate global development, as measured by the GSED DAZ scores, in survivors of neonatal sepsis assessed at one year of age.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/07/2025, St. George's Research Ethics Committee (SGREC) (St. George's Research Ethics Committee Joint Research and Enterprise Services Ground Floor, Jenner Wing City St. George's University of London Cranmer Terrace, London, SW17 0RE, United Kingdom; +44 (0)20 8725 5382; sgulrec@sgul.ac.uk), ref: 2025.0122

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied

Assessment of neurodevelopmental impairment in infants with neonatal sepsis

Interventions
The NeoSep LTFU1 study is a nested prospective cohort study that aims to recruit neonates from four sites in sub-Saharan Africa participating in the NeoSep1 randomised controlled trial (https://www.isrctn.com/ISRCTN48721236) and/or the SNIP-AFRICA neonatal infection surveillance study. This study will longitudinally assess the development of neonates treated for sepsis in the neonatal period using the GSED tool. The GSED short form (SF) will be adopted for NeoSep LTFU1. GSED assessments will be completed at days 28, 90, 180 and 360. The secondary outcome will be neurodevelopmental impairment at one year of age (DAZ score < 1.5) as a binary outcome.

Intervention Type
Not Specified

Primary outcome(s)
1. Development-for-Age Z (DAZ) score at one year of age (±30 days) measured using the Global Scales for Early Development Short Form (GSED SF) tool at days 28, 90, 180 and 360

Key secondary outcome(s)

Completion date
31/05/2029

Eligibility

Key inclusion criteria
1. Neonates enrolled to the NeoSep1 trial (https://www.isrctn.com/ISRCTN48721236) and/or SNIP-AFRICA surveillance study at a participating NeoSep LTFU1 site. All babies included in the study will have experienced at least one episode of clinical or culture positive sepsis as per the inclusion criteria of the parent studies.
2. Parent(s)/guardian(s) willing and able to provide consent for the study and provide follow-up information via telephone and/or in-person.

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
1 Days

Upper age limit
1 Months

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Neonates with co-morbidities and/or congenital abnormalities that are known or are likely to lead to severe NDI. The decision to exclude neonates will be at the discretion of the responsible clinician. Conditions that may lead to severe NDI include but are not limited to:
1.1. Severe hypoxic ischaemic encephalopathy
1.2. Chromosomal abnormalities e.g. Edwards syndrome (trisomy 18) or Patau syndrome (trisomy 13)
1.3. Severe microcephaly
2. Neonates known to have received a complete course of intravenous (IV) antibiotics for neonatal infection at another hospital prior to transfer to participating centres

Date of first enrolment
01/06/2026

Date of final enrolment
31/05/2028

Locations

Countries of recruitment
Ghana

South Africa

Tanzania

Uganda

Sponsor information

Organisation
City St George's, University of London

ROR
https://ror.org/047ybhc09

Funder(s)

Funder type

Funder Name
Gates Family Foundation

Alternative Name(s)
Gates Foundation, FUNDACIÓN DE LA FAMILIA GATES, Fundación Gates, GFF

Funding Body Type
Private sector organisation

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

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available