ISRCTN16979943 https://doi.org/10.1186/ISRCTN16979943

Studying infection prevention methods for infants admitted to neonatal hospital units

Submission date 31/05/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/08/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/08/2023	**Condition category** Neonatal Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Nearly 1 in 10 newborns in Europe is admitted to a neonatal intensive care unit in the first days of life – that is around 400,000 admissions every year.
Babies who stay in hospital are at risk of having bacteria that respond poorly to antibiotics on their bodies (called colonisation). Babies who are born before their due date and who need to stay in hospital for longer periods of time are at higher risk of acquiring such potentially harmful bacteria on their bodies.
The more babies on the unit that have harmful bacteria on their skin, the higher the risk that other babies will pick up these bacteria.
These activities are looking to count the number of babies that have different types of potentially harmful bacteria on their bodies at different time points. It will also look at how this may change over time.

Who can participate?
Babies and infants admitted to neonatal units at hospitals where this study is running.

What does the study involve?
On the day of the activity, the researchers will collect information about the medical history of each baby including how they were born, how long they have been in hospital, why they are in hospital, and any treatments they have received.
Each baby will have a poo sample collected from their nappy/diaper and a swab from various areas of their skin taken to check for any potentially harmful bacteria. These samples will be taken by medically trained staff who will be careful to avoid causing the baby any discomfort.
Each baby will only have these data and samples collected on the day of the activity,
Every baby will be assigned an anonymous identification number for these data and samples so they are kept secure and confidential.

What are the possible benefits and risks of participating?
There are no additional risks to the baby from standard of care. There are no benefits to the individual babies participating.

Where is the study run from?
1. Fondazione Penta Onlus (Penta) (Italy)
2. St George's University (UK)

When is the study starting and how long is it expected to run for?
April 2021 to October 2023

Who is funding the study?
European Union Horizon 2020

Who is the main contact?
Federica D'Ambrosio, federica.dambrosio@pentafoundation.org

Study website
https://neoipc.org/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
IRAS 306004

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 306004, CPMS 54655

Study information

Scientific Title
NeoIPC unit-level resistant bacterial colonisation surveillance

Acronym
NeoIPC

Study objectives
The NeoIPC colonisation assessment feasibility study is comprised of three activities: a colonisation assessment, survey of infection prevention and control (IPC) infrastructure and antimicrobial use in neonatal intensive care units (NICUs) in Europe.

This colonisation assessment aims to study the feasibility of assessing resistant bacterial colonisation pressure and modelling infant colonisation dynamics by using anonymous data and samples from repeated cross-sectional assessments collecting non-invasive samples (e.g., skin swabs and stool) that would typically be used as part of surveillance and quality management in NICUs. These samples will be analysed to establish colonisation pressure for clinically important resistant bacteria in a range of European neonatal intensive care units (NICUs).

The outcomes of this study will be used to support the design of the NeoIPC project Main trial - NeoDeco

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/11/2022, Yorkshire & the Humber - Sheffield Research Ethics Committee (NHS Blood and Transport Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, United Kingdom; +44 (0)207 1048210; sheffield.rec@hra.nhs.uk), ref: 22/YH/0282

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Study design
Observational multicentre set of surveillance activities consisting of a series of repeated cross-sectional assessment collecting non-invasive samples and survey data

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Assessment of bacterial colonisation pressure and colonisation dynamics in infants admitted to hospital neonatal units

Interventions
The target population for these surveillance activities are babies hospitalised in participating NICUs. Babies in all rooms of multi-room NICUs will be eligible.

Each participating NICU will be asked to complete all activities within a 4-week time window. The start of this window will be agreed with the central project management team.

NICUs will be expected to complete the following activities during the 6-week time window:

Completion of an infection prevention and control questionnaire online.
Four colonisation point prevalence surveys of skin swabs and stool samples with individual surveys to be minimum of 4 days and maximum of 14 days apart. Sites will be allocated in a random order of a 4-day, 7-day and 14-day gap between surveys.
Four antibiotic point prevalence surveys with a minimum of 4 and a maximum of 14 days apart. These do not necessarily need to be done on the same days as the colonisation surveys.
For the two types of point prevalence surveys, all babies present in the unit at 8 am on the day of the survey will be included in the survey.

Neonatal IPC questionnaire:
This questionnaire pertains to activity and practices at the level of the neonatal unit. The questionnaire will be completed once at the start of the study by each individual unit and will cover neonatal unit data from January 2022 – December 2022.

Colonisation point prevalence surveys:
To assess resistant bacterial colonisation, non-invasive microbiological samples (skin swabs and stool samples) will be collected from all contributing babies.
Each NICU will be allocated a specific unit identifying number by the study team. For multi-room NICUs, each room will have a unique number allocated for identification.
Patients will be anonymised with allocated participant ID numbers that allow for samples from the same baby over multiple survey to be linked and for samples to be linked to clinical data.
Colonisation assessment dates will be removed prior to analysis and the interval of days between assessments (e.g. 4 days) will be retained.
Brief clinical data will be collected with each sample. These clinical data are collected to assess resistant bacterial colonisation by clinical subgroups, most importantly stratified by prematurity (<32 weeks gestation vs ≥32 weeks gestation), surgical intervention and previous antibiotic exposure (any vs none).

Antibiotic use point prevalence surveys:
The primary data of interest are the antibiotic use pattern (e.g. drug utilisation 90% and Access /Watch/Reserve ratios) for babies hospitalised in participating NICUs.

In order to assess NICU antibiotic use patterns, up to four antibiotic PPSs will be conducted. These do not need to be conducted on the same day as the colonisation surveys. The schedule will be selected by the site and agreed with the project management team prior to starting.
All babies will be randomly allocated a participant ID number to allow for complete anonymisation of data.
All babies present in the participating NICU at 8 am on the day of the survey will be included in the survey (denominator of activity). All babies receiving an ongoing antibiotic prescription will have basic demographic information, underlying comorbidity data and antibiotic data collected.

Intervention Type
Other

Primary outcome measure
1. Proportion of babies exposed to antibiotics measured using Antibiotic Use Questionnaire conducted at four survey timepoints through the 25-day duration of the study defined by the site team
2. Prevalence of resistant bacterial colonisation measured using Colonisation Questionnaire and stool and skin swab sample collection, conducted at four survey timepoints through the 25-day duration of the study defined by the site team

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2021

Completion date
31/10/2023

Eligibility

Key inclusion criteria
The target population for these surveillance activities are babies hospitalised in participating NICUs. Babies in all rooms of multi-room NICUs will be eligible.

Neonatal intensive care units:
At the level of the NICUs, the only inclusion criterion is the routine care of extremely premature babies (e.g. those <28 weeks gestational age).

Babies – colonisation point prevalence survey surveillance:
All babies present in a participating NICU at 8 am on the morning of the day of the colonisation point prevalence surveys will be considered eligible with no clinical exclusion criteria. In fact, to establish colonisation pressure it is essential that a majority of babies on the unit at the time of survey be included. Babies whose parents specifically request that their baby does not contribute samples will be excluded.

Babies – antibiotic use surveillance:
An antibiotic point prevalence survey will be conducted of all babies admitted to a participating NICU at 8 am on the day of the survey. Data on prescribed antibiotics will be collected for all babies with an active (ongoing) antimicrobial prescription at that time. Babies present but not receiving antibiotics will contribute to the denominator.

Participant type(s)
Patient

Age group
Neonate

Lower age limit
0 Days

Upper age limit
1 Years

Sex
Both

Target number of participants
This is a unit level study and so does not have individual participant recruitment targets; participating units expected: 31

Key exclusion criteria
Babies whose parents specifically request that their baby does not contribute data or samples

Date of first enrolment
01/10/2021

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

Estonia

Germany

Greece

Italy

Poland

South Africa

Spain

Switzerland

United Kingdom

Study participating centre
St Mary's Hospital
Manchester
United Kingdom
M13 9WL

Study participating centre
Norfolk and Norwich University Hospital NHS Foundation Trust
Norwich
United Kingdom
NR4 7UY

Study participating centre
Charlotte Maxeke Johannesburg Academic Hospital
Johannesburg
South Africa
2193

Study participating centre
Tygerberg Hospital, Cape Town
Cape Town
South Africa
7505

Sponsor information

Organisation
PENTA Foundation

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Sponsor type
Charity

Website
http://penta-id.org/the-foundation.html

ROR
https://ror.org/00d7mpc92

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The participating sites will receive a descriptive summary of their data for their site and overall, within 6-12 months of the completion of data entry from all sites.

There are two guiding principles regarding the publication of any data generated through the surveillance activity:

Transparency – all sites contributing data will be informed as to the use of surveillance data, which may or may not include their own NICU data.

Quality – A centralised publication and abstract vetting and approval process within the NeoIPC project will maintain a high quality of overall scientific output.

All abstracts and manuscripts are to be approved by Project Management Team (PMT), Sponsor and the NeoIPC WP2 (Trial) and WP4 (Microbiology) partners before submission for presentation

or publication. The lead partners for NeoIPC WP2 (Trial) may request a delay in submission for presentation or publication if the presented analysis or results could compromise the primary objective of the planned NeoDeco Trial. The NeoIPC Project Management team will resolve any problems of authorship and will maintain the quality of publications as outlined in the NeoIPC Publication Policy. All publications will acknowledge the trial's funding sources by including the statement provided by the funder and displaying the relevant logos on posters and presentations.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository [Individual participant data].

The IPC questionnaire and the clinical data associated with the colonisation and the antibiotic surveys will be collected using REDCap, a secure, web-based platform for data collection hosted at St George's, University of London. Access to the database is restricted by role-based log-ons and sites will be able to view data only from their sites for all components of the study. Data collected on eCRFs will be compliant with regulatory requirements, following the principles of GCP and the General Data Protection Regulation (GDPR).

All project data will be handled in accordance with Good Clinical Practice (GCP) and General Data Protection Regulation 2016 (GDPR). When site-specific data are presented, these will be made available only in aggregate form and will be coded to prevent sites from being identified.

Surveillance data will be only accessible to authorised personnel who require the data to fulfil their duties within the scope of the project. Babies are only identified by a unique participant number and this is not linked to any patient-identifiable data once babies are discharged or the study period ends (whichever is earlier). Data will be archived in a secure server behind the SGUL firewall for 10 years for quality management purposes at the end of the study (see section 6.1.1).

The NeoIPC Colonisation assessment study uses an opt-out consent methodology.

Biological material in this project is not identified by participant name but by a unique participant ID. Each sample will also have a unique numeric identifier that is linked with the participant ID number. Once collected, biological material will be appropriately stored in a restricted area in the local laboratory at each site only accessible to authorised personnel until sample shipment to the Central Laboratory in Antwerp can be arranged. Upon arrival at the Central Laboratory the samples collected for the study will be kept at -80°C for a maximum period of 10 years after the end of the study in the UA-UZA Hub of the "Biobank Antwerpen" (BB190007) at the Laboratory of Medical Microbiology (University of Antwerp). Samples are stored in a dedicated electronically recorded location in a controlled access repository with constant temperature and environmental monitoring. These samples will only be kept for the conduct of additional scientific research performed in the objective of this protocol. Further research will under no circumstances concern human genetic material.

Upon project completion, the Ethics Committee at each site and St. George's, University of London is notified within 90 days.

Individual participating investigators will not have any inherent right to perform analyses or interpretations or to make public presentations or seek publication of any of the data other than

under the auspices of and with the approval of the NeoIPC Project management team. However, they will be encouraged to propose analyses subject to the approval of the NeoIPC Project Management team. Any requests for access to raw data will be welcomed as long as they are scientifically valid and do not conflict with the integrity of the trial or ongoing analyses by the trial team.

Anonymisation
For the colonisation point prevalence surveys, babies will be allocated participant numbers to allow for samples and basic clinical data from the same baby across multiple surveys to be linked (if applicable). For the antibiotic point prevalence surveys, patients will be allocated a random participant number at each survey and data from babies contributing to multiple surveys will not be linked.

The ID number should be marked down at site corresponding with internal identifiers to allow for the same number to be used for participants who are present for multiple colonisation surveys and for quality control processes in case of questions regarding data.

Any trackers held at sites associating participant numbers with patient identifiable information will be destroyed after the baby is discharged from the unit once data entry is complete (maximum 5 days after discharge) or at the end of the 6-week activity window at the site, whichever comes earlier. This is typical of IPC surveillance activities, for example the ECDC HAI-PPS and similar activities in countries outside of the European Union.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 2.0	04/01/2023	02/06/2023	No	No
Participant information sheet	version 2.0	12/12/2022	02/06/2023	No	Yes