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The clinical features, antimicrobial susceptibility patterns and genomics of bacteria causing neonatal sepsis in a children's hospital in Vietnam

Submission date
11/05/2017

Recruitment status
No longer recruiting

Registration date
06/06/2017

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Neonatal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Neonatal sepsis is a blood infection that occurs in babies younger than 90 days old. Antibiotics are used to treat bacterial infections but some bacteria have become resistant to antibiotics. In Vietnam little is known about the clinical features of neonatal sepsis, antibiotic susceptibility and resistance, and how these impact on disease and outcome. To address this, the aim of this study is to assess the clinical characteristics of babies with sepsis and to investigate the bacteria causing sepsis, including their resistance to antibiotics.

Who can participate?
Babies aged under 1 month with sepsis

What does the study involve?
The clinical characteristics of babies with sepsis are recorded and blood samples are taken to study the bacteria causing sepsis and their susceptibility to antibiotics. The impact of specific bacteria and antibiotic resistance on patient outcomes (mortality, length of stay and cost of treatment) is assessed.

What are the possible benefits and risks of participating?
The results of this study could be used to improve the treatment of bloodstream infections and run further studies focused on preventing sepsis. This is a minimal risk study because it does not involve any new drugs or treatments. The collection of all blood samples for use in this study is performed as part of routine clinical assessments and is consistent with the local standard of care and good clinical practice.

Where is the study run from?
Children's Hospital 1 and the Oxford University Clinical Research Unit (OUCRU-VN) (Vietnam)

When is the study starting and how long is it expected to run for?
August 2016 to December 2020

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr Toan Nguyen

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19EN

Study information

Scientific Title
The clinical features, antimicrobial susceptibility patterns and genomics of bacteria causing neonatal sepsis in a children’s hospital in Vietnam: an observational prospective study

Study objectives
There are limited contemporary data on the causes of bacterial sepsis in neonates in Vietnam. The trialists hypothesize that there has been a dramatic surge in multi-drug resistant Gram-negative organisms and the emergence of methicillin-resistant Staphylococcus aureus (MRSA).

The aim is to investigate the clinical features, major causes of neonatal sepsis, distribution of pathogens, their antimicrobial susceptibility patterns and the genomics of bacteria as well as their association with disease outcome.

The trialists hope that by studying and defining aetiology, antimicrobial susceptibility patterns and disease outcome they will be able to develop an improved approach to managing neonatal sepsis and will use these data to initiate intervention studies focused on preventing bloodstream infections with antimicrobial resistant pathogens in neonates with sepsis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Tropical Research Ethics Committee (OxTREC), 04/08/2016, ref: 35-16

Study design
Observational prospective study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Neonatal sepsis

Interventions
An observational prospective study to characterize the clinical features of neonates with sepsis, the microbial population structure, antimicrobial susceptibility patterns and the antimicrobial resistance genes of the bacteria causing that sepsis. Routinely, the investigators record on the paper case report form the data including demographic, clinical and laboratory information of the patients, the date of blood draw, the number of blood culture bottles inoculated, the result of the culture (whether positive or negative) and the susceptibility of the isolate to commonly used antimicrobial agents. Data from these records are subsequently entered into CliRes Data Management System of Oxford University Clinical Research Unit. These will be source data for this study. The number of patients admitted to the hospital annually will be obtained from hospital records. As part of this study all isolates from blood are stored and archived at -800C. These isolates will be re-cultured and the identification will be re-confirmed. Selected isolated organisms from blood will have further molecular characterization at a later date.

Intervention Type
Other

Primary outcome measure
1. Clinical characteristics of neonates with sepsis, recorded on a case report form during hospital stay from admission to discharge
2. The etiology of neonatal sepsis and the distribution of pathogens by clinical departments, assessed using the blood culture results including the isolation and identification information recorded on a case report form during hospital stay from admission to discharge
3. Antimicrobial susceptibility and resistance of isolated bacteria, assessed using disc testing, minimum inhibitory concentrations, conventional PCR and genome sequencing of resistance genes, during hospital stay from admission to discharge
4. The impact of specific bacteria and antimicrobial resistance profile on patient outcomes (mortality, length of stay and cost of treatment), recorded on a case report form during hospital stay at day 7, day 14, day 21 and day 28 after admission and at discharge
5. Genome sequence profile of isolated bacteria, assessed using Illumina whole genome sequencing at the end of recruitment

Secondary outcome measures
1. Antimicrobial resistance profile and gene distribution of the isolated bacteria by clinical departments, assessed using disc testing, minimum inhibitory concentrations, conventional PCR and genome sequencing of resistance genes, at the end of recruitment
2. The population structure of the isolated bacteria, the antimicrobial resistance gene pool and other horizontally transferred DNA, assessed by genome sequencing at the end of recruitment

Overall study start date
03/08/2016

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Neonates (≤1 month of age)
2. Diagnosis of probable sepsis or confirmed sepsis
3. Have blood culture taken
4. Inpatient at local hospital between 2017 and 2018
5. Informed consent given by parents or guardians

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants

800

Key exclusion criteria
Informed consent not given

Date of first enrolment
02/01/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Viet Nam

Study participating centre
Oxford University Clinical Research Unit
Viet Nam
700000

Sponsor information

Organisation
Oxford University Clinical Research Unit

Sponsor details
764 Vo Van Kiet Street
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Sponsor type
Research organisation

Website
http://www.oucru.org

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study will be reported according to the STROBE guidance for reporting observational studies. The contributions of all investigators will be recognized in authorship allocation. The authors (and their respective positions in the author list) will be agreed prior to the start of the study in accordance with the guidelines of the International Committee of Medical Journal Editors. Data from this study is of substantial interest to the scientific and clinical research communities. In line with Wellcome Trust policy that the results of publicly-funded research should be freely available, manuscripts arising from this study will, wherever possible, be submitted to peer-reviewed journals which enable Open Access via UK PubMed Central (PMC) within six months of the official date of final publication. All publications will acknowledge the trial's funding sources. In line with research transparency and greater access to data sharing policy of Oxford University Clinical Research Unit in Vietnam will be implemented. This policy is based on a controlled access approach with a restriction on data release that would compromise an ongoing trial or study. Data exchange complies with Information Governance and Data Security Policies in all of the relevant countries.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	24/01/2018		Yes	No
Results article	results	02/09/2022	06/02/2023	Yes	No