ISRCTN18160232 https://doi.org/10.1186/ISRCTN18160232

A study of multidrug-resistant organisms in adult intensive care units in Vietnam

Submission date
13/02/2020

Recruitment status
No longer recruiting

Registration date
17/02/2020

Overall study status
Completed

Last Edited
17/02/2020

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Healthcare-associated infections (HCAI) affect up to 10% of hospital patients and are associated with an increased risk of death. Multidrug-resistant organisms (MDRO) are more common in hospitals, and these organisms cause infections that cannot be treated by a number of antibiotics. Therefore HCAI infections are often very difficult to treat and it would be helpful to identify which drugs these organisms are resistant to in order to provide the best care for patients. Patients in intensive care units (ICU) are particularly vulnerable to HCAI, and several outbreaks of infection with MDRO have been reported.

Current practices for screening for MDRO vary between countries, hospitals, and units, reflecting a lack of information, and uncertainty about best practice. One strategy to reduce HCAI in ICUs would be to perform screening tests to look for MDRO in patients admitted to ICUs. This would enable earlier identification and treatment of MDRO and the implementation of appropriate infection control measures to prevent their spread.

Whole-genome sequencing (WGS) is a novel technology, which is more discriminatory than currently available methods. We are conducting a study to determine the rates of carriage, infection, and transmission of MDRO in the adult ICUs at the National Hospital for Tropical Diseases and Bach Mai Hospital, Hanoi, Vietnam, using WGS. All patients admitted to ICU during the study period will be screened for MDRO and clinical data on infections and antimicrobial use will be collected. This study will facilitate the translation of this technology from a research tool into day-to-day clinical practice. Information from this study will be used to inform infection control and public health policies and procedures.

Who can participate?
Patients over 18 years old admitted to the NHTD ICU or Bach Mai Hospital ICU

What does the study involve?
All patients admitted to the adult intensive care units (ICU) at the National Hospital for Tropical Diseases and Bach Mai hospital were eligible to participate in the study. After giving written informed consent participants' will have routine samples (taken from stool, urine, sputum and wound swabs in addition to any other samples taken as part of routine clinical care) screened for

carriage of multidrug-resistant organisms (MDRO) on admission to ICU, on discharge from ICU and weekly during their ICU stay. There will be no additional investigation or treatment beyond standard care as part of this trial.

What are the possible benefits and risks of participating?
This is an observational study with no direct risks or benefits for study participation. There are no differences in treatment for those participating in the study. All specimens will be collected by experienced nursing staff, in accordance with routine clinical practice.

Where is the study run from?
The National Hospital for Tropical Diseases (Viet Nam) and Bach Mai Hospital (Viet Nam)

When is the study starting and how long is it expected to run for?
June 2017 to February 2018

Who is funding the study?
The Medical Research Council (MRC) Newton Fund (UK) and the Ministry of Science and Technology (Viet Nam)

Who is the main contact?
Dr Estee Torok
et317@cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Estee Torok

ORCID ID
http://orcid.org/0000-0001-9098-8590

Contact details
University of Cambridge
Department of Medicine
Box 157
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 01223 336845
et317@cam.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Whole-genome sequencing (WGS) to determine multidrug-resistant organisms (MDRO) causing hospital-acquired infection in Vietnam: the Vietnam ICU WGS study

Acronym
Vietnam ICU WGS

Study objectives
What are the rates of colonization and transmission of multidrug-resistant organisms in the adult intensive care unit at the National Hospital for Tropical Diseases, Hanoi, Vietnam?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/12/2016, Ethical Review Board of Biomedical Research of National Hospital for Tropical Diseases, Vietnam, ref: 241/NDTW-TCCB
2. Approved 12/01/2017, Ethical Review Board of Biomedical Research of Bach Mai Hospital, Vietnam, ref: 133/CV-BM
3. Approved 19/06/2017, University of Cambridge Human Biology Research Ethics Committee (17 Mill Lane, Cambridge, CB2 1RX; cb480@admin.cam.ac.uk), ref: HBREC.2017.09

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
Surveillance of multi-drug resistant organisms, whole-genome sequencing, hospital-acquired infection

Interventions
All patients admitted to the adult intensive care units (ICU) at the National Hospital for Tropical Diseases and Bach Mai hospital were eligible to participate in the study.

After giving written informed consent participants' will have routine samples screened for carriage of multidrug-resistant organisms (MDRO) on admission to ICU (baseline), on discharge from ICU and weekly during their ICU stay (day 7, 14, 21, etc.). The samples analyzed by whole-genome sequencing (WGS) will include:
1. Stool samples (or rectal swab if stool sample unavailable)
2. Urine samples
3. Sputum or tracheal aspirates
4. Wound swabs (if applicable)
5. Additional diagnostic specimens taken as clinically indicated, such as blood cultures, cerebrospinal fluid, pleural fluid, ascitic fluid and joint aspirates

Additionally, environmental samples will be collected weekly (at baseline, 7, 14, 21, 28 days) using swabs from the following areas of the intensive care unit:
1. Door handles of patient rooms
2. Taps in patient rooms or adjacent to patient beds
3. Bed rails
4. Ventilation equipment
5. Patient tables
6. Computer keyboards

All specimens will be assigned a unique anonymized identification number prior to transfer to the research laboratory of NHTD for processing. Specimens will be cultured on selective media for the following target organisms:
1. Vancomycin-resistant enterococci (VRE)
2. Extended spectrum beta-lactamase producing Enterobacteriaceae (ESBL)
3. Carbapenem-resistant organisms (CRO)

Samples that are positive for suspected target organisms will undergo identification using MALDI TOF MS and antimicrobial susceptibility using Vitek-2 system. Isolates that are confirmed to be target organisms will undergo DNA extraction and storage at -80°C. DNA extracts will be transferred in batches to the Wellcome Trust Sanger Institute for DNA library preparation and high-throughput microbial whole-genome sequencing.

Intervention Type
Not Specified

Primary outcome measure
1. Number of patients colonized with MDRO is measured using laboratory analysis of samples taken at baseline, and weekly until discharge
2. Number of patients with clinical evidence of infection with MDRO is measured using laboratory analysis of samples taken at baseline, and weekly until discharge
3. Number of transmission events of MDRO is measured using laboratory analysis of samples taken at baseline, and weekly until discharge

Secondary outcome measures
1. Risk factors for colonization/infection with MDRO are measured using patient notes and demographic information and laboratory analysis of samples taken at baseline, and weekly until discharge
2. Outcomes for patients colonized/infected with MDRO is measured using patient notes and laboratory analysis of samples taken at baseline, and weekly until discharge

Overall study start date
01/01/2017

Completion date
01/07/2018

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Admitted to the NHTD ICU and Bach Mai Hospital ICU during the study period
3. Agree to participate in research and sign the consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
All adults admitted to the intensive care units during the study period (N=400)

Key exclusion criteria
Does not fulfill study inclusion criteria

Date of first enrolment
26/06/2017

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
Viet Nam

Study participating centre
National Hospital for Tropical Diseases
78 Giai Phong Street, Dong Na
Hanoi
Viet Nam
N/A

Study participating centre
Bach Mai Hospital
78 Giai Phong Street, Dong Na
Hanoi
Viet Nam
N/A

Sponsor information

Organisation
University of Cambridge

Sponsor details
School of Clinical Medicine
Box 111
Addenbrooke's Hospital
Hills Road,
Cambridge
England
United Kingdom
CB2 0QQ
+44 01223 766362
jo.dekkers@admin.cam.ac.uk

Sponsor type
University/education

Website
http://www.cam.ac.uk/

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
Newton Fund

Alternative Name(s)
The Newton Fund, NF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Ministry of Science and Technology

Alternative Name(s)
Ministry of Science and Technology of the Socialist Republic of Vietnam, Vietnamese Ministry of Science and Technology, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Viet Nam

Results and Publications

Publication and dissemination plan
Data are being analyzed and will be presented and published in 2020.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Data sharing statement to be made available at a later date