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Hospital-acquired infections and antibiotic drug resistance in a Vietnamese hospital

Submission date
16/07/2008

Recruitment status
Stopped

Registration date
17/07/2008

Overall study status
Stopped

Last Edited
14/11/2013

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
As healthcare around the world improves and more people are given access to treatment, two new problems emerge: the problem of nosocomial infections and the problem of antimicrobial resistance. Nosocomial infections, also known as hospital-acquired infections, are diseases that are more likely to happen in a hospital environment. They can be diseases that are circulating among doctors, nurses and hospital staff that then get passed on to patients, or diseases that are just more likely to strike people who are already sick. Antimicrobial resistance is the phenomenon of bacteria becoming resistant to the drugs used against them. When an antibiotic drug is used, the bacteria who are resistant will survive and go on to reproduce, while the bacteria who are not resistant perish, so in the end only the bacteria who are resistant remain circulating among people. These two problems are predicted to become increasingly important in Vietnam in the coming years. Advances in hospital care mean patients will come to hospitals more frequently and stay at hospitals longer each time, meaning they will be more exposed to environments in which nosocomial infections occur. Improved access to treatment means more patients will be given antibiotic drugs, increasing the likelihood of bacteria becoming resistant. This study aims to look at how often nosocomial infections occur, as well as how much of the bacteria circulating currently are drug-resistant.

Who can participate?
Patients were recruited to the study from the intensive care unit (ICU) of the National Institute of Infectious and Tropical Diseases (NIITD). Recruited patients had to be adults over 16 years old and had to provide informed consent.

What does the study involve?
This was an observational study, so patients were not given new or extra treatments, they were simply observed and analyzed. Study doctors would take swabs from a patient on admission to the ICU and once per week until discharge. The samples would be stored and analyzed for development of nosocomial infections or antimicrobial resistance.

What are the possible benefits and risks of participating?
The patient may benefit from the study because more intensive investigations are being done which may allow to detect and treat an infection earlier than otherwise. This research involves

several tests that are done routinely in these hospitals. There are no major risks. The swabs may cause some slights discomfort but otherwise will cause the patient no harm. Some people may find the weekly visits until discharge inconvenient. There will be no additional costs to the patient if they participate in this study. The study investigators will cover all the costs of any tests undertaken as part of the study.

Where is the study run from?
This study was planned by researchers at the Oxford University Clinical Research Unit in Vietnam, in partnership with the National Institute of Infectious and Tropical Diseases.

When is the study starting and how long is it expected to run for?
Unfortunately this study could not be conducted and no patients were enrolled.

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

Who is the main contact?
Clinical Trials Unit at the Oxford University Clinical Research Unit in Vietnam
Tel: +84 839 241 983

Contact information

Type(s)
Scientific

Contact name
Dr Heiman Wertheim

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ctu04avjun08

Study information

Scientific Title
Antimicrobial resistance and nosocomial infections at the Intensive Care Unit of the National Institute of Infectious and Tropical Diseases (NIITD), Hanoi: an observational study

Study objectives
To study the pattern and burden of antimicrobial resistance and nosocomial infections in the intensive care unit of National Institute of Infectious and Tropical Diseases (NIITD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending as of 16/07/2008 from:
1. Oxford Tropical Medicine Research Ethics Committee (OXTREC) (UK)
2. NIITD Ethical Committee (Viet Nam)

Study design
Observational descriptive 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Nosocomial infections

Interventions
The study investigations will consist of bacterial culture from nose swabs, rectal swabs and sputum on admission and once per week until discharge to monitor development of antibiotic resistance. If other specimens for bacterial culture are taken for clinical reasons, these results will be entered onto the database. These specimens will also be stored.

Updated 14/11/2013: This study was never conducted as local approval could not be obtained.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. Proportion of patients colonised with resistant bacteria on admission
2. Rate of acquisition of resistant bacteria during admission
3. Incidence of nosocomial infections (nosocomial infections under investigation are: pneumonia, blood stream infection, urinary tract infection and Clostridium difficile diarrhoea)

Secondary outcome measures
Compare patient characteristics between:
1. Patients who develop nosocomial pneumonia versus those who do not
2. Patients who develop nosocomial blood stream infection versus those who do not
3. Patients who develop nosocomial urinary tract infection versus those who do not
4. Patients who develop Clostridium difficile associated diarrhoea versus those who do not, and
5. Patients with resistant bacteria versus those without

Overall study start date
01/11/2008

Completion date
01/11/2010

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Adult patients, including pregnant women, admitted to the intensive care unit of NIITD
2. Aged over 16 years, both male and female
3. Informed consent signed by the patient or his/her legal guardian

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
Absence of informed consent

Date of first enrolment
01/11/2008

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Viet Nam

Study participating centre
National Institute of Infectious and Tropical Diseases (NIITD)
Hanoi
Viet Nam
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Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 077078)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration