

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

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| Submission date 16/07/2008 | Recruitment status Stopped | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 17/07/2008 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 14/11/2013 | Condition category Infections and Infestations | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 slight 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

Contact details

National Institute of Infectious and Tropical Diseases (NIITD)

78 Giai Phong Street

Hanoi

Viet Nam

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+84 4 576 4320

hwertheim@oucru.org

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