

Outpatient antibiotic overuse in acute respiratory infections (ARI) in Children's Hospital No. 1, Viet Nam

Submission date 16/07/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 17/07/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/11/2020	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

Background and study aims

A recent study in the Outpatient Department in Childrens Hospital N°1, Viet Nam showed that about 85% of outpatients with acute respiratory infections were prescribed antibiotics because more specific (microbiologic) diagnostics usually take too long, and physicians choose to treat all possible treatable diagnoses while waiting for results. Therefore, this study was conducted to collect data that will allow us to make retrospective conclusions on appropriate or inappropriate use of antibiotics, and will help in determining at which pathogen rapid diagnostic tests should be aimed in order to effectively reduce the use of antibiotics by prescribing physicians.

Who can participate?

Children less than 16 years of age presenting to the Outpatient Department in Childrens Hospital N°1 with acute respiratory infections, not admitted to the hospital and living in Ho Chi Minh city.

What does the study involve?

Nose, throat and rectal swabs and blood, stool and urine samples will be collected, along with information on symptoms and antibiotics used.

What are the possible benefits and risks of participating?

All research investigations will be paid for. In addition, there will be a contribution towards the costs of consumables as well as transport for follow up.

Where is the study run from?

The study is run by researchers at the Oxford University Clinical Research Unit (OUCRU) Viet Nam; and Outpatient Department in Childrens Hospital No1, Ho Chi Minh City, Vietnam.

When is the study starting and how long is it expected to run for?

The study ran from February 2009 to February 2010.

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

Who is the main contact?
The Clinical Trials Unit at the Oxford University Clinical Research Unit Viet Nam
+84 839241983

Contact information

Type(s)
Scientific

Contact name
Dr Rogier van Doorn

Contact details
The Oxford University Clinical Research Unit (OUCRU)
Hospital for Tropical Diseases
190 Ben Ham Tu
Ho Chi Minh City
Viet Nam
Q5
+84 8 924 1983
rvandoorn@oucru.org

Additional identifiers

Protocol serial number
ctu03avjun08

Study information

Scientific Title
Outpatient antibiotic overuse in acute respiratory infections (ARI) in Children's Hospital No. 1, Viet Nam

Study objectives
The generated data will allow us to make retrospective conclusions on appropriate or inappropriate use of antibiotics, and will help in determining at which pathogen rapid diagnostic tests (Point of Care) should be aimed in order to effectively reduce the use of antibiotics by prescribing physicians.

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) (ref: 31/08)
2. Childrens Hospital No. 1 (Viet Nam)

Primary study design

Observational

Study design

Prospective descriptive study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Acute respiratory infections (ARI)

Interventions

Specimen collection:

1. 1 nasopharyngeal aspirate (NPA)
2. 1 nose swab
3. 1 throat swab
4. 1 rectal swab
5. Capillary blood (3 drops on filter paper)
6. Urine sample: 10 ml
7. Symptoms and signs
8. Antibiotics used

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. To quantify the inappropriate antibiotic use in outpatient acute respiratory infections in Children's Hospital No. 1, Viet Nam
2. To identify the most common viral and bacterial aetiologies associated with inappropriate antibiotic use

Key secondary outcome(s)

1. To assess epidemiology, aetiology, (pre) treatment, clinical features and outcomes acute respiratory infections in outpatients
2. To assess the short-term effect of antibiotic use on the selection of resistant bacteria in the rectal swabs

Completion date

01/02/2010

Eligibility**Key inclusion criteria**

1. Aged less than 16 years, either sex
2. Diagnosis of acute respiratory infections (ARI)
3. Not admitted to the hospital

4. Informed consent by parents or legal guardians
5. Living in Ho Chi Minh City and agreeing to return for follow up visit after 1 week

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 Years

Sex

All

Total final enrolment

563

Key exclusion criteria

1. Having underlying illness (except asthma)
2. Previous admission within 3 months (in any hospital or health centre)
3. No consent given

Date of first enrolment

01/02/2009

Date of final enrolment

01/02/2010

Locations

Countries of recruitment

Viet Nam

Study participating centre

The Oxford University Clinical Research Unit (OUCRU)

Ho Chi Minh City

Viet Nam

Q5

Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Charity

Funder Name

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

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/11/2020	05/11/2020	Yes	No