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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/07/2008	**Overall study status** Completed	
Last Edited 05/11/2020	**Condition category** Respiratory	

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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Prospective descriptive 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 below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2009

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

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
500 patients

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)

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

Study outputs

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