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Educational interventions on reducing antibiotic over-prescribing among children with upper respiratory infections (URIs)

Submission date
17/06/2015

Recruitment status
No longer recruiting

Registration date
23/06/2015

Overall study status
Completed

Last Edited
06/02/2019

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Over-prescribing antibiotics is a serious issue globally. It is also very common among children with acute upper respiratory tract infections. It has left many children suffering from bacterial resistance due to irrational use of antibiotics, especially in less developed rural areas. Antibiotics are widely abused in China, especially in rural areas. However, few studies have focused on this area in developing countries including China. The aim is to carry out a study in rural Guangxi, China to test an effective approach of reducing over-prescribing antibiotics for upper respiratory infections (URTIs) among children.

Who can participate?
Parents/caregivers and doctors who have been taking care of children between 2-14 years old

What does the study involve?
The 25 participating township hospitals in two counties of Guangxi province, China, are randomly allocated into one of two groups. The hospitals in the control group continue usual management according to the current national guidelines. The hospitals in the intervention group receive an educational intervention for both clinicians and parents. Clinicians receive antibiotic use guidelines, training on antibiotic use, and an antibiotics use appraisal in the monthly hospital staff meeting. Parents receive specific short messages and printed educational material describing rational antibiotic use during clinical consultations, and videos about rational antibiotic use play in the education area at the hospitals. A questionnaire survey is conducted to see the changes in clinicians' knowledge, attitude and practice before and after the intervention in each group. Interviews and group discussions take place to see if this study is feasible and acceptable with the intervention package. Effectiveness is assessed through the difference in the antibiotic prescription rate before and after the intervention and between the intervention and control groups.

What are the possible benefits and risks of participating?
This study may help to reduce irrational antibiotic use among clinician, increase knowledge on antibiotic use among rural caregivers/parents, improve the management of antibiotic use for policy makers, and change prescription behaviours of health providers. No risks are expected.

Where is the study run from?
China Global Health Research and Development, as the leading centre, is in collaboration with Guangxi Provincial Center for Disease Control, the University of Leeds, the Chinese University of Hong Kong and Shandong University.

When is the study starting and how long is it expected to run for?
June 2015 to March 2016

Who is funding the study?
China Programme, COMDIS Health Services Delivery Research Consortium

Who is the main contact?
Prof. Xiaolin Wei
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Educational interventions on reducing antibiotic over-prescribing among children with upper respiratory infections (URIs): a clustered randomized controlled trial in rural Guangxi, China

Study objectives
Current hypothesis as of 03/07/2017:
Educational interventions on both clinicians and parents are effective on reducing over-prescribing antibiotics for childhood upper respiratory infections (URIs).

Previous hypothesis:
Educational interventions on both clinicians and parents are effective on reducing over-prescribing antibiotics for childhood upper respiratory infections (URIs) and acute bronchitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Guangxi Provincial Centre for Disease Control and Prevention, 13/09/2014, ref: GXIRB2014-0036
2. University of Leeds, School of Medicine, Research Ethics Committee, 11/02/2016, ref: MREC15-016

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Upper respiratory infections (URIs) among children, which includes: acute URIs, common cold, acute tonsillitis and acute pharyngitis

Interventions

Current interventions as of 03/07/2017:
The township hospitals randomly allocated into the intervention group will receive the educational intervention for both clinicians and parents.

For clinicians:
1. Operational guidelines (based on Chinese antibiotic use guidelines, IMCI, and the NICE guideline, we will focus on but not limit to URIs)
2. Systematic training for clinicians in township hospitals on rational antibiotic use
3. Antibiotics use appraisal in the monthly hospital staff meeting

For parents:
1. Specific short messages to be given during clinical consultations by doctors.
2. Printed educational material describing rational antibiotic use for childhood URIs
3. Videos to play in the education area at township hospitals, describing rational antibiotic use for childhood URIs

The control group will continue usual management according to the current national guidelines. Treatment is provided according to existing knowledge and antibiotics are given at the individual clinician's discretion, while no systematic health education is provided.

Previous interventions:
The township hospitals randomly allocated into the intervention group will receive the educational intervention for both clinicians and parents.

For clinicians:
1. Operational guidelines (based on Chinese antibiotic use guidelines, IMCI, and the NICE guideline, we will focus on but not limit to URIs)
2. Systematic training for clinicians in township hospitals on rational antibiotic use
3. Antibiotic prescription rate (APR) reminder - social media message reminders once a month by pharmacist
4. Antibiotics use appraisal in the monthly hospital staff meeting
5. Health education to patient caregivers: specific short messages to be given during clinical consultations

For parents:
1. Printed educational material describing rational antibiotic use for childhood URIs
2. Videos to play in the education area at township hospitals, describing rational antibiotic use for childhood URIs

The control group will continue usual management according to the current national guidelines. Treatment is provided according to existing knowledge and antibiotics are given at the individual clinician's discretion, while no systematic health education is provided.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 03/07/2017:
Antibiotics prescription rate (APR) of outpatient childhood URIs between 2-14 years old, measured at baseline (3 months prior to the intervention) and endline (last 3 months during intervention period)

Previous primary outcome measures:
Antibiotics prescription rate (APR) of outpatient childhood URIs between 2-14 years old, measured at baseline (3 months prior to the intervention), 3 months after the intervention and 6 months after the intervention

Secondary outcome measures
Current secondary outcome measures as of 03/07/2017:
Measured at baseline (3 months prior to the intervention) and endline (last 3 months during intervention period):
1. Two and more than two antibiotic combination prescription rate
2. Broad-spectrum antibiotic use rate of outpatient prescriptions
3. Injectable antibiotic prescription rate
4. Quinolones use rate
5. Average cost of a prescription

Previous secondary outcome measures:
Measured at baseline (3 months prior to the intervention), 3 months after the intervention and 6 months after the intervention:
1. Two and more than two antibiotic combination prescription rate
2. Broad-spectrum antibiotic use rate of outpatient prescriptions
3. Quinolones use rate
4. Average cost of a prescription
5. Antibiotics prescription rate of inpatient childhood URIs
6. Appropriateness of antibiotics use among inpatient childhood URIs

Overall study start date
15/06/2015

Completion date
30/12/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/07/2017:
All eligible township hospitals from the two selected counties of Guangxi who agree to participate in the study will be included. The two counties should have implemented the Essential Medicine List and Zero-markup policy in 2012.

Intervention:
1. Township hospitals: 25 township hospitals in two selected counties
2. Parents/caregivers: who have been taking care of children between 2 and 14 years old
3. Doctors: pedestrian or internal medicine clinician who is seeing children between 2 and 14 years old

Research:
1. Parents/caregivers: 2 parents/caregivers per township hospital in 6 township hospitals selected for process evaluation.
2. Doctors: 1 township hospital director and 3 clinicians per township hospital in 6 township hospitals selected for process evaluation.
3. Prescriptions: 200/township hospital (before and after intervention respectively)

Previous inclusion criteria:
All eligible township hospitals from the two selected counties of Guangxi who agree to participate in the study will be included. The two counties should have implemented the Essential Medicine List and Zero-markup policy in 2012.

Intervention:
1. Township hospitals: 25 township hospitals in two selected counties
2. Parents/caregivers: who have been taking care of children between 2 and 14 years old
3. Doctors: pedestrian or internal medicine clinician who is seeing children between 2 and 14 years old

Research:
1. Parents/caregivers: 6-8 parents/caregivers in each focus group discussion
2. Doctors: 1 township hospital director and 2 clinicians in each township
3. Prescriptions: outpatients: 40/township (before and after intervention), inpatients: 200 /township (before and after intervention)

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
25 clusters, each cluster requires at least 200 prescriptions at baseline and endline period respectively

Key exclusion criteria
1. Prescriptions for children diagnosed with diseases such as tuberculosis, HIV/AIDS or other immunodeficiency disease, any form of cancer, dyslipidaemia, chronic heart diseases, and pneumonia, who need long-term antibiotic treatment or prophylaxis
2. Children ≤2 years old and >14 years old will be excluded

Date of first enrolment
25/06/2015

Date of final enrolment
25/09/2015

Locations

Countries of recruitment
China

Study participating centre

25 township hospitals
Rong county and Liujiang
China
-

Sponsor information

Organisation
China Programme, COMDIS Health Services Delivery Research Consortium

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1032 Dongmen Bei Rd
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China
518003

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
COMDIS Health Services Delivery Research Consortium

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer reviewed journals including:
1. Main outcomes of the trial
2. Trial process evaluation
3. Cost-effectiveness of the trial
Expected to be published by the end of 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Xiaolin Wei (xiaolin.wei@utoronto.ca).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/05/2016		Yes	No
Results article	results	01/12/2017		Yes	No
Results article	results	05/02/2019		Yes	No