ISRCTN96892547 https://doi.org/10.1186/ISRCTN96892547

Reducing inappropriate antibiotic prescribing for acute respiratory tract infections using an antibiotic training and management program led by local hospitals in China

Submission date
31/07/2019

Recruitment status
No longer recruiting

Registration date
18/08/2019

Overall study status
Completed

Last Edited
12/12/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Antimicrobial resistance has become a serious public health issue worldwide. It is mainly caused by prescribing antibiotics to people who do not need them or prescribing the wrong kind of antibiotic for the type of infection. Acute upper respiratory tract infections (RTIs), which includes colds, sore throats, laryngitis (lost voice) and sinus infections, and lower respiratory tract infections, such as chest infections and bronchitis, are commonly treated with antibiotics, especially in primary care facilities (township hospitals and village clinics). However, antibiotics are not necessary and usually do not help clear the illness. This study aims to investigate a way of working that targets doctors, pharmacists, and other healthcare professions as well as patients to try to reduce inappropriate prescribing of antibiotics for RTIs with the help of electronic medical records (EMR) and the WeChat app in rural Guangdong, China.

Who can participate?
Healthcare staff in township hospitals and patients diagnosed with acute RTIs.

What does the study involve?
The 34 participating township hospitals in two counties of Guangdong province, China, are randomly allocated into one of two arms. The township hospitals in the control arm continue usual care according to the current national guidelines.
The township hospitals in the intervention group receive an intervention package for both healthcare staff and patients. Township hospital doctors and the village doctors will receive guidelines on the appropriate use of antibiotics, key health messages and referral suggestions in both printed and WeChat app versions during a training session. An improved electronic prescription system will help to remind township hospital doctors to prescribe antibiotics cautiously. Township hospitals will establish an antimicrobial stewardship work team to hold monthly meetings to assess doctors' prescriptions for acute RTIs with a standard procedure

using EMR and the WeChat app. Patients in the intervention group will receive educational materials about appropriate antibiotic use and will be invited to link with the township hospital WeChat public account to encourage better communication.

What are the possible benefits and risks of participating?
This study may help to reduce unnecessary antibiotic use by doctors in township hospitals, increase knowledge on antibiotic use among rural patients and their caregivers, and improve the antimicrobial stewardship and prescription behaviours of health providers. No risks are expected.

Where is the study run from?
Guangzhou Institute of Respiratory Health (China) and the University of Toronto (Canada), in collaboration with Yuebei People's Hospital (China)

When is the study starting and how long is it expected to run for?
January 2019 to February 2024

Who is funding the study?
The study is supported by the Beijing Life Oasis Public Service Center, directly supervised by the Life Oasis Public Welfare Fund Management Committee of the China Primary Health Care Foundation.

Who is the main contact?
1. Dr. Chao Zhuo, chao_sheep@263.net/chaosheep@sina.com
2. Prof. Xiaolin Wei, xiaolin.wei@utoronto.ca

Contact information

Type(s)
Public

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Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GD AB Trial

Study information

Scientific Title
Reducing inappropriate antibiotic prescribing for acute respiratory tract infections through a comprehensive antibiotic stewardship in primary care facilities: a clustered randomised controlled trial and follow-up study in rural Guangdong, China

Study objectives
Current study hypothesis as of 12/02/2020:
In the intervention arm, inappropriate prescribing of antibiotics for acute respiratory tract infections (RTIs) would be reduced through interventions based on a comprehensive antibiotic stewardship program for primary care facilities in rural China, as compared by usual care in the control arm. The antibiotic stewardship program consists of guideline development and training, peer review of prescriptions, improved electronic medical records (EMR) and smart app communication, and patient education. The interventions would be feasible and sustainable in rural China that to be used for future scale-up.

Previous study hypothesis:
In the intervention arm, inappropriate prescribing of antibiotics for acute respiratory tract

infections (RTIs) would be reduced through interventions based on a comprehensive antibiotic stewardship program for primary care facilities in rural China, as compared by usual care in the control arm. The antibiotic stewardship program consists of guideline development and training, peer review of prescriptions, improved electronic medical records (EMR) and smart app communication, correct-dose dispensing in the pharmacies, and patient education. The interventions would be feasible and sustainable in rural China that to be used for future scale-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 14/02/2020:
1. Approved 06/02/2020, University of Toronto Office of Research Ethics (McMurrich Building, 12 Queen's Park Crescent West, 2nd Floor, Toronto, ON M5S 1S8 Canada; ethics.review@utoronto.ca; +1 416 946-3273), ref: 38265
2. Approved 18/11/2019, Ethics Committee of the First Affiliated Hospital of Guangzhou Medical University (29th Floor, New Building of the First Affiliated Hospital of Guangzhou Medical University, 151 Yanjiang Road, Guangzhou, Guangdong Province 510120, China; kyglkgyfyy@163.com; +86 020-83062938), ref: 2019-53

Previous ethics approval as of 12/02/2020:
1. Approved 06/02/2020, University of Toronto Office of Research Ethics, ref: 38265
2. Approved 18/11/2019, Ethics Committee of the First Affiliated Hospital of Guangzhou Medical University, ref: 2019-53

Previous ethics approval:
1. Submitted 30/07/2019, University of Toronto Office of Research Ethics
2. Submitted 30/07/2019, Ethics Committee of the First Affiliated Hospital of Guangzhou Medical University

Study design
Interventional prospective unblinded multicentre pragmatic cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

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

Acute respiratory tract infections, including acute upper respiratory tract infections and acute bronchitis

Interventions

Current interventions as of 12/02/2020:
All recruited township hospitals will be stratified by county and be randomized into the intervention or control group in an overall 1:1 ratio with a 9:8 ratio within each county. The control group will continue usual care according to the current national guidelines. Treatment will be provided according to existing knowledge and antibiotics will be given at the individual clinician's discretion. The intervention will last for 12 months followed by a 24-month follow-up during the post-intervention period.

The intervention group will receive an intervention package target on both health care providers and patients including the following:

For healthcare provider:
1. Improved antibiotic stewardship (AMS) in each township hospital that includes an AMS team established to determine AMS policies in the institute and an AMS working group to hold monthly peer review meetings on prescriptions for acute RTIs with a standard procedure using EMR and WeChat app
2. Operational concise guidelines for RTIs based on Chinese antibiotics use guidelines, IMCI, British Thoracic Society/ NICE guidelines, and American Association of Pediatrics guidelines covering the contents of patient symptom-based diagnostic algorithms, appropriate use of antibiotics, key health education messages and referral suggestions provided for township hospital and village doctors in both printed and WeChat app version
3. Training on operational guideline and communication skills for township hospital and village doctors and an innovatively developed program embedded in the WeChat app to monitor and review antibiotics prescribing in each township hospital
4. An improved electronic prescription system including an embedded clinical decision module to prescribe antibiotics carefully, an alarm system to suggest necessary tests, and pop-ups to recommend appropriate antibiotics when an antibiotic is needed

For patient:
1. Educational materials in both printed and WeChat app versions will be provided for patients with acute RTIs
2. An invitation to link their WeChat personal accounts to the township hospital WeChat public account for better communication

Previous interventions:
All recruited township hospitals will be stratified by county and be randomized into the intervention or control group in an overall 1:1 ratio with a 8:9 ratio within each county. The control group will continue usual care according to the current national guidelines. Treatment will be provided according to existing knowledge and antibiotics will be given at the individual clinician's discretion. The intervention will last for 12 months followed by a 24-month follow-up during the post-intervention period.

The intervention group will receive an intervention package target on both health care providers and patients including the following:

For healthcare provider:
1. An improved antibiotic stewardship (AMS) in each township hospital that includes an AMS

team established to determine AMS policies in the institute and an AMS working group to hold monthly peer review meetings on prescriptions for acute RTIs with a standard procedure using EMR and WeChat app
2. Operational concise guidelines for RTIs based on Chinese antibiotics use guidelines, IMCI, British Thoracic Society/ NICE guidelines, and American Association of Pediatrics guidelines covering the contents of patient symptom based diagnostic algorithms, appropriate use of antibiotics, key health education messages and referral suggestions provided for township hospital and village doctors in both printed and WeChat app version
3. Training on operational guideline and communication skills for township hospital and village doctors, reading chest X-ray reports from radiologists and an innovatively developed program embedded in the WeChat app to monitor and review antibiotics prescribing in each township hospital
4. Improved electronic prescription system including an embedded clinical decision module to prescribe antibiotics carefully, an alarm system to suggest necessary tests, and pop-ups to recommend appropriate antibiotics when an antibiotic is needed
5. Dispensing prescription-specific doses of antibiotics in township hospital

For patient:
1. Educational materials in both printed and WeChat app versions will be provided for patients with acute RTIs
2. An invitation to link their WeChat personal accounts to the township hospital WeChat public account for better communication

Intervention Type
Behavioural

Primary outcome measure
Proportion of prescriptions for acute RTIs that contain any antibiotic.
All primary and secondary outcomes will be collected from electronic medical records at baseline (12 months before intervention), intervention period (12 months) and long-term follow-up period (24 months after intervention).

Secondary outcome measures
Current secondary outcome measures as of 12/02/2020:
1. Broad-spectrum antibiotic prescription rate
2. Fluoroquinolones prescription rate
3. Prescription rate for multiple antibiotics
4. Intravenous injection antibiotic prescription rate
5. The proportion of prescriptions containing any antibiotics in the Access group of the WHO's 2019 Essential Medicine List classification
6. The proportion of prescriptions containing any Traditional Chinese Medicines
7. The proportion of prescriptions containing any glucocorticoids
8. The average cost of a prescription
9. The average cost of a consultation

Previous secondary outcome measures:
1. Broad spectrum antibiotic prescription rate
2. Prescription rate for broad spectrum antibiotics excluding amoxicillin-clavulanic acid
3. Prescription rate for multiple antibiotics
4. Intravenous injection antibiotic prescription rate
5. Prescription rate for alternative medicines

6. Average cost of a prescription
All primary and secondary outcomes will be collected from electronic medical records at baseline (12 months before intervention), intervention period (12 months) and long-term follow-up period (24 months after intervention).

Overall study start date
01/01/2019

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Healthcare professionals:
1. Physicians, pharmacists, radiologists and directors in enrolled township hospitals in two selected counties in Shaoguan City, Guangdong Province who agree to participate in the study

Patient/caregivers:
1. Patients aged 0-75 years diagnosed with acute RTIs and/or their caregivers

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
0 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
34 clusters, each cluster requires prescriptions of all eligible patients (at least 100 per cluster)

Total final enrolment
287128

Key exclusion criteria
Township hospitals:
1. Township hospitals that have participated in the pilot study

Patients:
1. Non-acute RTI
2. Pneumonia
3. Chronic conditions including asthma, COPD, non-infective or non-acute disorders

4. Immunological deficiencies
5. Tuberculosis
6. Any form of cancer

Date of first enrolment
01/03/2020

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
China

Study participating centre
34 township hospitals
Lechang county and Nanxiong county
Shaoguan
China
512000

Sponsor information

Organisation
First Affiliated Hospital of Guangzhou Medical University

Sponsor details
Guangzhou Institute of Respiratory Health
National Clinical Research Center of Respiratory Disease
First Affiliated Hospital of Guangzhou Medical University
151 Yanjiang Road
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510120
+86-20-83062888
hysggyx@163.com

Sponsor type
Hospital/treatment centre

Website
https://www.gyfyy.com/

ROR

https://ror.org/00z0j0d77

Funder(s)

Funder type
Other

Funder Name
Beijing Life Oasis Public Service Center

Results and Publications

Publication and dissemination plan
Planned academic publications include main trial results, process evaluation and economic evaluation, and a follow-up study of all participants to determine long-term effect and sustainability of interventions. Results of the follow-up study will be reported in a separate paper from the trial results.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The anonymised patient level data and statistical code generated during and/or analysed during the current study will be available upon reasonable request to Prof. Xiaolin Wei (xiaolin.wei@utoronto.ca) or Dr. Chao Zhuo (chao_sheep@263.net) after all papers of this study have been published and within 5 years after the trial ended. The data can only be used for research purposes and shared with research organizations/qualified researchers. Consent for data use will be obtained during patient recruitment. Confidential agreements must be signed between applicants and local hospitals before data sharing according to local policy requirements.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/05/2020	14/05/2020	Yes	No