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Respiratory tract infections in primary care

Submission date 24/08/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/09/2012	**Overall study status** Completed	
Last Edited 18/11/2021	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Despite the fact that general practitioners (GPs) and pediatricians know that antibiotics are not indicated for patients suffering from cough, sore throat, earache, or common cold, in primary care antibiotics are too often prescribed for patients with symptoms of acute respiratory infections. There are two reasons for that. First of all doctors perceive that their patients desire antibiotics. Secondly, doctors worry that their patients might develop complications that need be treated with antibiotics anyway. This study tests two procedures to help GPs and pediatricians to optimize prescribing of antibiotics.

Who can participate?
This study includes more than 90 GPs and 90 pediatricians in two German regions. Patients visiting those physicians for an episode of acute respiratory tract infection are asked to agree that data of their symptoms, medication and course of disease may be recorded and scientifically analyzed. More than 30,000 patients who visit their GP or pediatrician with cough, sore throat, earache, or common cold are expected to be followed up.

What does the study involve?
During three successive winter periods patients who visit their GP or pediatrician for acute respiratory infection and who are insured with the German statutory health insurance company AOK are included. Doctors are randomly allocated to one of three groups: (1) an intervention that includes communication training, (2) an intervention that combines communication training with training in using point-of-care tests which may help them to rule out a severe infection, or (3) to a control group with care as usual. Antibiotic prescription rates among all three groups are compared. Data on reconsultation rates, complications and hospital admissions are also analyzed.

What are the possible benefits and risks of participation?
Patients of both groups may benefit from their doctor's increased awareness of unnecessary antibiotic prescriptions. In the best case, patients benefit from decreasing rates of inappropriate antibiotic usage. To control for any negative effect of the interventions a study monitor team checks for complications and hospital admissions. An unexpected but theoretically possible increase of complications due to reduced antibiotic prescriptions can lead to the study stopping.

Where is the study run from?
Universities of Rostock and Freiburg (Germany)

When is the study starting and how long is it expected to run for?
February 2012 to February 2016

Who is funding the study?
German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung [BMBF])

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01GY1140

Study information

Scientific Title
Converting habits of antibiotic prescribing for respiratory tract infections in German primary care: the randomized controlled CHANGE-2 trial

Acronym
CHANGE-2

Study objectives
The CHANGE-2 trial will test the effectiveness of two interventions (communication training and point-of-care testing [POCT]) aiming at the reduction of inappropriate antibiotic prescriptions for adults and children suffering from respiratory tract infection (RTI) in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Medicine Rostock Ethics Committee, September 2012

Study design
Three-arm cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory tract infection (RTI)

Interventions
Clusters will consist of participating primary care physicians and their patients. Physicians will be randomized into three groups:
1. Intervention A (communication training)
2. Intervention A+B (communication training + point-of-care testing [POCT])
3. Control (care as usual)

Communication training will be organized within one-time small group sessions and will focus on the following topics: Patient expectations and shared decision-making (SDM). In particular, participating physicians will ameliorate their communication techniques in order to explore patients' (or parents') expectations. Also, they will be trained in patients' concepts of disease and patients' actual needs, e.g. ruling out a serious disease or pain relief. Furthermore, an adapted concept of delayed prescribing will be presented to participating physicians.

Physicians randomized into intervention A+B will be encouraged to use POCT kits (CRP and RADT) in accordance to provided clinical algorithms.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Physicians' antibiotic prescription rate for RTI derived from data of the statutory health insurance AOK that covers more than 50 % of the population in the study regions

Key secondary outcome(s))
1. Re-consultation rate
2. Use of medical services
3. Hospital admissions

Completion date
29/02/2016

Eligibility

Key inclusion criteria
The trial includes general practitioners and practice-based pediatricians and their patients, who ask for consultation due to acute respiratory infection.

Patient inclusion criteria are:
1. Health insurance with the AOK, a statutory health insurance that covers more than 50% of the population in the study regions
2. Three months minimum age
3. Physician consultation visit due to the first episode of acute RTI (upper respiratory infection (URTI) and lower respiratory infection (LRTI)) according to the ICD classes: J00-J04, J06, J13, J20, J22, otherwise healthy. This definition will include all typical acute RTI including bronchitis, tonsillopharyngitis (e.g. sore throat), and otitis media.
Participants are required to give informed consent that includes the acceptance of scientific use of relevant data stored at the AOK. This data will include the period of 12 months before and 6 weeks after recruitment into the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Underlying chronic diseases, which may affect the immune status in any relevant matter (e.g. malignoma, chronic obstructive pulmonary diseases, cystic fibrosis, immune deficiency of other causes)
2. Patients who are not able to give informed consent
3. Patients who require hospital care

Date of first enrolment
01/10/2012

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Germany

Study participating centre
Rostock University Medical Center
Rostock
Germany
18055

Sponsor information

Organisation
German Aerospace Center [DLR] (Germany)

ROR
https://ror.org/04bwf3e34

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/12/2012		Yes	No
Interim results article		29/09/2020	18/11/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes