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Reducing antibiotic resistance through adequate use of antibiotics

Submission date	**Recruitment status**	[_] Prospectively registered
24/10/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/12/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/10/2020	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

With an average prescription rate of 30-40%, antibiotics are still too frequently prescribed for respiratory tract infections in German outpatient care. The over-prescription of antibiotics is often explained by an overestimation of patient's expectations regarding antibiotic treatment. This study will test the effectiveness of the RESIST intervention, which provides information to physicians and patients about the development of antibiotic resistances. The major aim of the trial is to reduce the rate of inappropriate antibiotic prescriptions for patients suffering from acute respiratory tract infections (ARTI) in German primary care.

Who can participate?

Primary care physicians from Germany will be recruited for this study, and the data of all patients consulting participating physicians due to an episode of ARTI between July 2017 to June 2019 will be used

What does the study involve?

In order to participate in RESIST, it is compulsory for the physicians to complete an online training course comprising three modules. Module one covers physician-patient communication. It aims at enabling the physician to properly assess and deal with patient's expectations. Module two and three focus on rational antibiotic therapy in case of upper and lower respiratory tract infections. It is intended that the physicians subsequently apply their acquired skills in their daily consultations. After the successful completion of an online exam, the physician receives posters, leaflets, and brochures on rational antibiotic therapy, which can be used during consultations and /or displayed in the waiting area. Physicians are rewarded for the completion of the online training course with a one-time payment and for the “extended” consultation services with a fixed lump sum provided that a minimum number of 20 patients per quarter is treated within the study.

In order to examine if the RESIST intervention has an effect on the prescription of antibiotics among patients with ARTI, the antibiotic prescription rate for ARTI for all physicians of the intervention group is compared to the antibiotic prescription rates of a control group. Data is derived from the Central Research Institute of Ambulatory Health Care in Germany. Additional qualitative research will investigate how the project is perceived and implemented by physicians, patients and medical staff.

What are the possible benefits and risks of participation?
Patients benefit from their physician's increased awareness of unnecessary antibiotic prescriptions and extended consultation services. Ideally, patients and society in general benefit from decreasing rates of inappropriate antibiotic usage and a slowed development and spread of antibiotic resistance.
There are no known risks to participants taking part in this study.

Where is the study run from?
Institute for General Practice, Rostock University Medical Center (Germany)

When is the study starting and how long is it expected to run for?
December 2016 to March 2020

Who is funding the study?
Innovation Fund of the Federal Joint Committee (G-BA) (Germany)

Who is the main contact?
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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
01NVF16005

Study information

Scientific Title
RESIST: Reducing antibiotic RESISTance through adequate use of antibiotics for acute respiratory tract infections

Acronym
RESIST

Study objectives
The trial tests whether the RESIST intervention (including elements of doctor-patient communication and knowledge transfer) is more effective in reducing antibiotic prescribing for ARTI in children and adults than care as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the Rostock University Medical Center, 29/06/2017, Reference: A 2017-0090

Study design
Interventional non-randomised trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Acute respiratory tract infection

Interventions
Participating physicians will complete an online training course (CME acknowledged), that focuses on doctor-patient communication, shared decision-making and rational antibiotic therapy among patients suffering from ARTI. The successful completion of the course is remunerated. It is intended that the physicians apply their acquired skills in their daily consultation.
Furthermore, informational material such as leaflets, posters and brochures are provided. These can be used during the consultation or displayed in the waiting area. Physicians are assumed to apply the acquired competencies from their training course in their daily patient consultations. This is incentivised by a remuneration.

Intervention Type
Behavioural

Primary outcome measure
Physicians' overall annual antibiotic prescription rate (regardless of the diagnosis), for all patients insured with a substitute health fund before and after the intervention. This is obtained from routine healthcare data from the "Central Research Institute of Ambulatory Health Care in Germany“ (Zi), assessed using 2016 data (before the intervention), 2017 data and 2018 Q1 data (available 28/02/2019) and 2018 Q2, Q3 and Q4, and 2019 Q1 data (available 31/12/2019)

Secondary outcome measures
1. Annual antibiotic prescription rate per practice/physician for all patients insured with one of the substitute health funds diagnosed with ARTI before and after the RESIST intervention
2. Quality of antibiotic prescription practice measured by internationally accredited quality indicators (ESAC-Net indicators)
3. A process evaluation, focusing on the practical feasibility of the RESIST program, assessed using:
3.1. Focus group discussions with physicians participating in RESIST between January and July 2017
3.2. Telephone interviews with patients treated by a participating physician due to ARTI between January and July 2017

Overall study start date
15/12/2016

Completion date
14/03/2020

Eligibility

Key inclusion criteria
Patients:
1. Aged 1 year or older
2. Health insurance with a substitute health fund
3. Physician consultation visit due to ARTI (upper respiratory infection (URTI) and lower respiratory infection (LRTI))
4. Otherwise healthy

Physicians:
1. General practitioners, pediatricians and otorhinolaryngologists
2. Registration with any participating “Association of Statutory Health Insurance Physicians” located in Bavaria, Baden-Wuerttemberg, Lower Saxony, North Rhine, Westphalia-Lippe, Brandenburg, Mecklenburg-Western Pomerania and Saarland

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
3,000 primary care physicians treat an estimated number of 480,000 patients with ARTI. All primary care physicians based in the participating regions who do not receive the intervention, along with their respective patients serve as control group.

Key exclusion criteria
Data of patients who meet at least one of the following criteria:
1. Underlying chronic diseases, which may affect the immune status in any relevant matter (e.g. chronic obstructive pulmonary diseases, cystic fibrosis, immune deficiency of other causes)
2. Pregnancy
3. Other relevant infectious diseases e.g. urinary tract infections

Date of first enrolment
01/04/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Germany

Study participating centre
Institute for General Practice, Rostock University Medical Center
Doberaner Str. 142
Rostock
Germany
18057

Sponsor information

Organisation
Association of Substitute Health Funds e.V. (vdek e.V.)

Sponsor details
Askanischer Platz 1
Berlin
Germany
10963

Sponsor type

Other

Website
https://www.vdek.com

Funder(s)

Funder type
Government

Funder Name
Innovation Fund of the Federal Joint Committee (G-BA)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact, peer-reviewed journal

Intention to publish date
14/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Central Research Institute of Ambulatory Health Care in Germany“ (Zi) (email: zi@zi.de) in the form of aggregated anonymised raw data from March 2020 to March 2025. Data will be shared upon request for the purpose of academic research and scientific analyses (such as meta-analysis). Consent was obtained from physicians and consent from patients was not obligated as the data was gathered and processed based §80 SGB X. Data will be pseudonymised and de facto anonymised routine data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/09/2020	05/10/2020	Yes	No