

# Reducing antibiotic resistance through adequate use of antibiotics

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>24/10/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>06/12/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>05/10/2020       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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?

Prof. Attila Altiner

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

### Study type(s)

Prevention

### 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(s)

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)

### Key secondary outcome(s)

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

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**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.)

# Funder(s)

## Funder type

Government

## Funder Name

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

# Results and Publications

## 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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 30/09/2020   | 05/10/2020 | Yes            | No              |