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Promoting rational antibiotic therapy in German primary care

Submission date
09/06/2022

Recruitment status
No longer recruiting

Registration date
22/07/2022

Overall study status
Completed

Last Edited
01/02/2023

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:
Antibiotic overuse is when antibiotics are used when they're not needed. Antibiotics are one of the great advances in medicine. But overprescribing them has led to resistant bacteria (bacteria that are harder to treat). Some germs that were once very responsive to antibiotics have become more and more resistant.
The rational use of antibiotics is of great importance in health care. In primary care, acute respiratory infections are the most common cause of inappropriate antibiotic prescribing. Since existing studies aiming to optimise antibiotic use are usually based on voluntary participation of physicians, general practitioners (GPs) with inappropriate prescribing behaviour are underrepresented. For the first time in Germany, the ElektRA study will assess and compare effects of three interventions on antibiotic prescribing rates for respiratory and urinary tract infections among high-prescribers in primary care.

Who is included in the trial?
Primary care physicians from one of the nine participating regional Associations of Statutory Health Insurance Physicians (Baden-Württemberg, Bavaria, Bremen, Hesse, Lower Saxony, North Rhine, Saarland, Schleswig-Holstein, Westphalia-Lippe) and with an antibiotic prescribing score less than 2.

What does the study involve?
ElektRA is a 4-arm cluster-randomised controlled trial among German GPs in nine regional Associations of Statutory Health Insurance Physicians. On their behalf the Central Research Institute of Ambulatory Health Care in Germany (Zi) analyses all outpatient claims and prescription data. Based on this data base, high antibiotic prescribing GPs are identified and randomised into four groups: A control group (N=2,000) and three intervention arms. We test social norm feedback on antibiotic prescribing (N=2,000), social norm feedback plus online training on rational prescribing practice and communication strategies (N=2,000), and social norm feedback plus online peer-moderated training on rational antibiotic prescribing, communication strategies and sustainable behaviour change (N=1,250). Primary outcome is the overall rate of antibiotic prescriptions. Outcomes are measured before intervention and over a period of 15 months after start of the intervention.

What are the possible benefits and risks of participation?
Physicians with high antibiotic prescribing rates gain awareness of their own prescribing behaviour. They are encouraged to reflect on this and motivated to change their prescribing behaviour. In this way, the risk of the non-rational prescribing practices can be reduced. Patients benefit from their physicians' increased awareness. 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?
Association of Substitute Health Funds (Vdek) e.V., Berlin, Germany

When is the study starting and how long is it expected to run for?
January 2021 to December 2024

Who is funding the study?
Innovation Fund of the Federal Joint Committee (G-BA) (Germany) (funding code: 01NVF20026)

Who is the main contact?
Maike Schulz, Central Research Institute of Ambulatory Health Care in Germany (Zi), Berlin, Germany (mschulz@zi.de)

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Promoting rational antibiotic therapy among high antibiotic prescribers in German primary care (ElektRA). A 4-arm cluster-randomised controlled trial

Acronym
ElektRA

Study objectives
The trial investigates the effects of three interventions on antibiotic prescribing rates for respiratory and urinary tract infections among high-prescribers in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2021, Ethics Committee of the Rostock University Medical Center, Approval-No. A 2021-0221 (St.-Georg-Str. 108, 18055 Rostock, Germany; +49 381 4949900; andreas.buettner@med.uni-rostock.de)

Study design
4-arm cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Acute respiratory and urinary tract infections

Interventions
Three interventions against the control group are tested: (A) personalised feedback on own prescribing behaviour in comparison to GPs of the region within a visual attention-grabbing graph (social norm feedback); (B) feedback like (A) plus a project's own online training (eLearning) on rational prescribing practice and communication strategies; (C) feedback like (A) plus an online peer-moderated training in quality circle format on the topic of rational antibiotic prescribing, communication strategies and development of individual starting points for a sustainable behaviour change.

The total duration of treatment is 3 months; the total duration of follow up is 15 months.

Randomisation into four groups (control group and three intervention arms A-C) will be stratified by regional Associations of Statutory Health Insurance Physicians (ASHIP) and will be carried out by the Central Research Institute of Ambulatory Health Care in Germany that is not involved in study conduct and implementation. For randomisation the sql-code, which assigns a random number to all included GPs, is used. The individual GP-random number combinations, ranging from ni to m (number of all GPs that need to be included), are sorted according to the following scheme: If the random number is between 1 and n1 the corresponding GP is assigned to Group A (n1= defined number of GPs in that group), if it is between n1+1 and n2 the GP is assigned to Group B. The procedure for group C and the control group is analogous, whereas m-ni describes the size of the control group. GP-random number combinations greater than m are not assigned to any group.

Intervention Type
Behavioural

Primary outcome(s)
Physicians' overall rate of antibiotic prescriptions, measured as the proportion of patients with antibiotic prescriptions out of all patients with a prescription before intervention and after it starts

Key secondary outcome(s))
Physicians' overall prescription rates before and after the intervention for cephalosporins and fluoroquinolones separately

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. General practitioners (GP)
2. Registered as physician with the "Association of Statutory Health Insurance Physicians" located in Baden-Wuerttemberg, Bavaria, Bremen, Hesse, Lower Saxony, North Rhine, Saarland, Schleswig-Holstein, Westphalia-Lippe
3. Prescription sum score >2 (sum score ranges from 0 to 6; a GP or GP practice obtains one or two points if its own value in one of the following aspects exceeds the 75% percentile of antibiotic prescribing within the respective region:
3.1. Overall prescription rate (ratio of patients with antibiotic prescriptions to patients with any prescription), one point
3.2. Prescription rate for upper respiratory tract infections (ratio of patients with upper respiratory tract infection to antibiotic prescriptions for these patients), one point
3.3. Prescription rate for lower respiratory tract infections (ratio of patients with lower respiratory tract infection to antibiotic prescriptions for these patients), one point
3.4. Prescription rate of fluoroquinolones; two points: Total prescription rate of fluoroquinolones (ratio of patients with fluoroquinolone to patients with antibiotic) and/or fluoroquinolone prescription rate for urinary tract infection (ratio of urinary tract infection patients with fluoroquinolone to urinary tract infection patients with antibiotics
3.5. Prescription rate of cephalosporins (ratio of patients with cephalosporin to patients with antibiotic); one point

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Participation on the predecessor project RESIST

Date of first enrolment
01/09/2022

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Germany

Study participating centre
Centreal Research Institute of Ambulatory Health Care in Germany (Zi)
Salzufer 8
Berlin
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10587

Study participating centre
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Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Innovation Fund of the Federal Joint Committee (G-BA) in Germany (funding code: 01NVF20026)

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. Data will be shared upon request for the purpose of academic research and scientific analyses (such as meta-analysis).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/10/2022	06/10/2022	Yes	No