Prescription of Antibiotics in pRimary CAre

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24668

Source
NTR

Brief title
PARCA

Health condition

We focus on the number of dispensed antibiotics, qualifying for respiratory tract infections, that are prescribed by GPs. Important to note is that the unit of analysis are the GPs and not the patients.

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, and the Municipal Health Service of Rotterdam-Rijnmond.
Source(s) of monetary or material Support: The Netherlands organization for health research and development (ZonMw)

Intervention

Outcome measures

Primary outcome

Our primary outcome is the number of dispensed courses of antibiotics qualifying for

respiratory tract infections, per 1000 registered patients.

For eligible antibiotics, we selected all first and second choice antibiotics that qualify for respiratory tract infections according to the Dutch antibiotic guidelines and expert opinion. This produced the following selection of eight antibiotics: Doxycycline (J01AA02), Amoxicillin (J01CA04), Augmentin (J01CR02), Phenoxymethylpenicillin (J01CE02), Sulphonamides with trimethoprim inclusive derivatives (J01EE), Macrolides (J01FA), Moxifloxacin (J01MA14), and Pheneticillin (J01CE05).

To evaluate the effect of the intervention, we will perform a one-way ANCOVA (analysis of covariance) in which we statistically control for the number of dispensed antibiotics at baseline and the differences between the intervention and the control group. The number of dispensed antibiotics at baseline for both groups will be compared with the number of antibiotics during the 6 months following the intervention. We will perform our analysis according to both an intention-to-treat (ITT) and a per-protocol (PP) analysis in which the GPs in the intervention arm who did not follow the training session, will be removed from the analysis.

Secondary outcome

The total number of dispensed courses of antibiotics for all infections (regardless of the origin), per 1000 registered patients.

Study description

Background summary

Although antibiotic use and antimicrobial resistance in the Netherlands is relatively low, inappropriate prescription of antibiotics is substantial. First generation non-western immigrants in the Netherlands are shown to be prescribed more antibiotics than native Dutch. However, they have been largely ignored in research and programs into antibiotic stewardship. General practitioners (GPs) experience pressure to prescribe antibiotics for immigrants, and they have difficulty to communicate in a cultural-sensitive way. Multifaceted interventions that include communication skills training for GPs are shown to be most effective in reducing antibiotic prescribing. Therefore, our study aims to develop and evaluate a tailored intervention for GPs and their immigrant patients.

Study objective

GPs who have learned to communicate in a cultural-sensitive way during the PARCA-intervention, prescribe less antibiotics than GPs who did not received the PARCA-intervention.

Study design

We will use data for the primary and secondary outcome from the following 6-month periods: November 2019 to April 2020 (baseline option 1); November 2020 to April 2021 (baseline option 2), and November 2021 to April 2022 (follow-up). Due to COVID-19 we include two options for the baseline period. In the first year after the emergence of COVID-19, it was shown that the number of antibiotic prescriptions in the Netherlands decreased significantly (van der Pol, 2021). We do not know whether the effect of the COVID-19 pandemic will continue in the coming years. Therefore, we have two baseline options. Because the control arm will not receive the intervention, it reflects the 'normal' situation regarding the number of dispensed antibiotics. If the primary outcome measure in the control arm during the follow up is closer to baseline option 1, we will use this as baseline for the trial; if it is closer to baseline option 2, we will use this as baseline for the trial.

We will collect data about individual background characteristics (e.g. gender, age, years of practice) via a registration questionnaire which the GPs receive at the intake of the study.

The E-learning for the GPs in the intervention arm will take place in Autumn 2021. One to two weeks after the E-learning, the GPs receive the evening training. The GPs in the control arm will receive the E-learning and the training session in Spring 2022, after the observation period for the trial.

In addition to our RCT we will perform a process evaluation, in which we obtain insight into the opinion of GPs regarding the improvement of their communication skills, the relevance of the training, and the applicability of the developed patient materials in practice. Also, we will ask them to rate their own cultural-sensitive communication skills, skills to assess patient expectations, and skills to explain non-prescription of antibiotics to immigrant patients, before and after the intervention. We will measure this using two online questionnaires. The first questionnaire will be filled in before the training and the second questionnaire three months afterwards.

Intervention

The intervention for the GPs will consist of three different components:
- An E-learning focused on intercultural skills with 4 lessons of 10-15 minutes each;
- An evening training session (3.5 hours) in which GPs will be taught intercultural skills, discuss video-taped consultations with intercultural doctor-patient interactions, and practice the newly learned skills during role plays with a training actor;
- Use of patient materials (written information and an animation movie that will be presented on the website Thuisarts.nl) for immigrant patients in their own language, to be used during consultation.

Contacts

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Eligibility criteria

Inclusion criteria

Dutch GPs/locums, with a specific focus on GPs who are located in or around Rotterdam, Amsterdam, The Hague and Utrecht.

Exclusion criteria

- Locums who work at diverse practices.
- Locums who work at one practice but who do not prescribe under their individual prescriber code.
- GPs from whom the individual prescriber code cannot be identified in the data.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021

Enrollment:	58
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
N/A

Ethics review

Positive opinion
Date:	02-05-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9450
Other	METC Erasmus MC : MEC-2020-0142

Study results

Summary results
N/A