Prescription of Antibiotics in pRimary CAre

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24668

Bron
Nationaal Trial Register

Verkorte titel
PARCA

Aandoening

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.

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam, and the Municipal Health Service of Rotterdam-Rijnmond.
Overige ondersteuning: The Netherlands organization for health research and development (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Erasmus MC
Dominique Lescure

0618293349

Wetenschappelijk

Erasmus MC
Dominique Lescure

0618293349

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	58
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	02-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A