ISRCTN11175879 https://doi.org/10.1186/ISRCTN11175879

Reducing antibiotic use in primary care: a pharmacist-led educational and audit & feedback strategy

Submission date 25/11/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/12/2024	**Overall study status** Ongoing	
Last Edited 21/07/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study aims to improve how general practitioners (GPs) prescribe antibiotics by providing them with educational support and feedback. The goal is to ensure antibiotics are used correctly to combat resistance and improve patient care.

Who can participate?
All general practitioners (GPs) working in primary health care centers in three Spanish Health Care Districts: Mallorca (Balearic Islands), Paterna (Valencia), and Tarragona-Reus (Catalonia) will participate. A total of 112 GPs are required for the study.

What does the study involve?
GPs will receive personalized feedback on their antibiotic prescribing habits, including information on selection, dosage, duration, and the conditions treated. Those who request additional help or are in the highest prescribing quartile will get one-on-one support from a study pharmacist. This includes setting goals, creating action plans, and discussing specific cases. Participants will also have access to an online educational course.

What are the possible benefits and risks of participating?
The main benefit is improved antibiotic prescribing practices, which can lead to better patient outcomes and reduced antibiotic resistance. There are no significant risks for the GPs participating in this study.

Where is the study run from?
The study is conducted in three Spanish Health Care Districts: Mallorca (Balearic Islands), Paterna (Valencia), and Tarragona-Reus (Catalonia).

When is the study starting and how long is it expected to run for?
January 2023 to December 2026

Who is funding the study?
The study is funded by the Carlos III Institute of Health (PI22/01742) (Spain)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A pharmacist-led educational intervention and audit & feedback approach to reduce antibiotic prescriptions in primary care

Acronym
AFA study

Study objectives
Current study hypothesis as of 06/01/2025:
An Audit & Feedback intervention targeting general practitioners (GP), which includes individualized graphical data on antibiotic prescriptions (covering antibiotic selection, dosages, treatment duration, and associated conditions) combined with a pharmacist-led educational intervention consisting of an individualized, face-to-face session with a primary care pharmacist for GPs with significant potential for improvement in their prescribing practices (above the 75th percentile), along with an online educational component, reduces antibiotic prescriptions by at least 1 point in the ratio of total antibiotic prescriptions per 100 visits, for individuals aged 14 years and older.

Previous study hypothesis:
An Audit & Feedback intervention targeting general practitioners (GP), which includes individualized graphical data on antibiotic prescriptions (covering antibiotic selection, dosages, treatment duration, and associated conditions) combined with a pharmacist-led educational intervention consisting of an individualized, face-to-face session with a primary care pharmacist for GPs with significant potential for improvement in their prescribing practices (above the 75th percentile), along with an online educational component, reduces antibiotic prescriptions by at least 4 daily doses per 1,000 inhabitants per day (DHD) in individuals over 14 years of age.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/07/2023, Balearic Islands Ethics Committee (c/Calçat, 2A, 2n, Palma, 07011, Spain; +34 971177378; ceic_ib@caib.es), ref: IB 5219/23 PI

Study design
Multicenter parallel randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Reduction of antibiotic prescription in primary care

Interventions
The method of randomization is simple random sampling.

General practitioners (GPs) in the intervention arm will receive individualized monthly information about their antibiotic prescription (incorporating graphical data, including antibiotic selection, dosages, treatment duration, and associated conditions), combined with an individualized, face-to-face intervention by a primary care pharmacist for GPs with significant potential for improvement in their prescribing practices (above the 75th percentile), along with an online educational component.

GPs in the control group will receive an intervention to reduce potentially inappropriate medication use (benzodiazepines, proton pump inhibitors and antipsychotics in patients with dementia) in patients over 65 years old.

The follow-up of the intervention is 12 months.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 06/01/2025:
The efficacy of the interventions on the prescription of antibiotics in the primary care area, measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up. The primary outcome will be measured as the total number of antibiotic prescriptions per 100 visits.

Previous primary outcome measure:
The efficacy of the interventions on the prescription of antibiotics in the primary care area, measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up

Secondary outcome measures
Current secondary outcome measures as of 07/05/2025:
1. Percentage of patients who start antibiotic treatment measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up.
2. Antibiotic prescription according to therapeutic group of antibiotics measured using number of antibiotic prescriptions according to therapeutic group (beta-lactams, glycopeptides, macrolides, aminoglycosides, tetracyclines, quinolones and fluoroquinolones, sulfonamides, lincosamides, oxazolidinones, polymyxins, rifamycins, nitroimidazoles, nitrofurans, fosfomycin) extracted from the e-prescription databases of each health district at 12-month follow-up.
3. Antibiotic prescription according to prescription pathology measured using the number of

antibiotic prescriptions and their associated pathology (lower and upper respiratory infections, lower and upper urinary tract infections, sexually transmitted infections, skin and soft tissue infections, oral and odontogenic infections) at 12-month follow-up.
4. Antibiotic prescription according to gender measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district, considering the gender of the GP and gender of the patient at 12-month follow-up.
5. The reach, engagement, adoption, fidelity and maintenance of the intervention. Reach will be defined as the percentage of participating GPs relative to the total number of eligible GPs. Engagement will measure the degree of active involvement in the intervention, including use of the feedback reports, participation in pharmacist-led sessions, and integration of recommendations into clinical practice. Adoption will be measured at the organizational level as the percentage of healthcare management units that have agreed to implement the intervention. Fidelity to the intervention will be assessed through audits of adherence to the planned feedback delivery process. This includes consistency in the timing and content of reports, implementation of pharmacist consultations, and completion of online training modules. Maintenance of the intervention will be assessed at 6 and 12 months post-intervention, focusing on the degree to which the intervention becomes institutionalized within the healthcare system.

Previous secondary outcome measures:
1. Percentage of patients who start antibiotic treatment measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up.
2. Antibiotic prescription according to therapeutic group of antibiotics measured using number of antibiotic prescriptions according to therapeutic group (beta-lactams, glycopeptides, macrolides, aminoglycosides, tetracyclines, quinolones and fluoroquinolones, sulfonamides, lincosamides, oxazolidinones, polymyxins, rifamycins, nitroimidazoles, nitrofurans, fosfomycin) extracted from the e-prescription databases of each health district at 12-month follow-up.
3. Antibiotic prescription according to prescription pathology measured using the number of antibiotic prescriptions and their associated pathology (lower and upper respiratory infections, lower and upper urinary tract infections, sexually transmitted infections, skin and soft tissue infections, oral and odontogenic infections) at 12-month follow-up.
4. Antibiotic prescription according to gender measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district, considering the gender of the GP and gender of the patient at 12-month follow-up.
5. The reach of the intervention as well as the fidelity of the intervention execution. The reach of the intervention will be measured using the percentage of patients assigned to GPs, with any antibiotic prescription and eligible to receive the intervention at 12 months follow-up. The fidelity will be measured using a comprehensive record with a detailed description of the execution process and any adaptations made in each intervention, as well as the strategies they comprise at the 12-month follow-up.

Overall study start date
01/01/2023

Completion date
12/12/2026

Eligibility

Key inclusion criteria

All GPs with assigned patients in their primary care health center will be included

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
112

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/05/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Spain

Study participating centre
Balearic Islands Health Service (IB-Salut)
Carrer de l'Escola Graduada, 3, Centre
Palma
Spain
07002

Study participating centre
Paterna Health District (Conselleria de Salut Universal; Arnau de Vilanova-Llíria district)
Paterna
Spain
46980

Study participating centre

Tarragona-Reus Health district (Institut Català de la Salut; Tarragona-Reus district)
Tarragona
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43480

Sponsor information

Organisation
Primary Care Management of Mallorca (Gerencia de Atención Primaria de Mallorca)

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Sponsor type
Government

Website
https://www.ibsalut.es/es/servicio-de-salud/organizacion/gerencias-ibsalut/gerencia-de-atencion-primaria-mallorca

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Spain

Results and Publications

Publication and dissemination plan
1. The effectiveness of the intervention will be published in a Primary Care/General Medicine journal
2. The factibility, feasibility and fidelity will be published in a Primary Care journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/07/2025	21/07/2025	Yes	No