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Collaborative deprescribing intervention of Proton-Pump Inhibitors among community-dwelling older adults: The C-SENIoR trial

Submission date
12/06/2023

Recruitment status
No longer recruiting

Registration date
14/06/2023

Overall study status
Completed

Last Edited
04/11/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Increasing life expectancy is a positive achievement, but it also brings challenges. Older adults often have poor health and chronic conditions, which means they take medicines that can be harmful. Proton-pump inhibitors (PPI) are medications that can cause problems for older people, such as fractures, unnecessary emergency visits, and hospitalizations. Despite this, PPIs are still prescribed too often for older adults.

Preventing harm from medications is a global challenge for patient safety. Deprescribing is an approach that aims to reduce the number of medications and improve their use for patients. It involves healthcare professionals supervising the process of reducing or stopping medications that may be causing harm or no longer providing benefits. The goal is to optimize medication use and improve patient outcomes. While there is evidence supporting the withdrawal of PPIs, it can be challenging to stop using certain medications for various reasons. The value of deprescribing is still uncertain, which raises questions about its widespread implementation.

This study aims to evaluate how effective and cost-effective it is when community pharmacists and general practitioners work together to stop the inappropriate use of PPIs among older adults living in the community in Portugal.

Who can participate?
People aged 65 years old or over with more than 8-weeks continuous PPI use, registered at the Family Health Units of interest, and with access to a telephone (fixed line or mobile phone) that agree to participate.

What does the study involve?
This study is conducted in outpatient care and involves two groups (groups 1 and 2). In Group 1, pharmacies and their neighborhood Family Health Units (FHUs) are working together to deliver a collaborative intervention to identify and discontinue the long-term unnecessary and unsafe use of PPIs among their older patients. In group 2, pharmacies and the FHUs provide the usual care they normally offer to their patients.

Both participants in groups 1 and 2 are recruited in community pharmacies. In group 1, in addition to what the health professionals normally do when the patients ask for a PPI, patients are asked about the PPI clinical indication and receive an educational brochure from the pharmacist explaining the benefits and harms of the long-term use of these medicines. Then they are referred to the general practitioner (GP) in the engaged FHUs. GPs receive the pharmacist's first assessment/recommendations and book a patient's appointment for the PPIs' clinical assessment and possible discontinuation. The decision is discussed with the patient and a withdrawal strategy is defined. The pharmacist is informed by the GP about the clinical decision and the adopted strategy. Thus, the pharmacist does the patients' follow-up to monitor the deprescribing process and the management of any possible symptoms that arise from the withdrawal of the PPI.

What are the possible benefits and risks of participating?
Participating in the trial offers several potential benefits. For patients in the experimental group (group 1), who are using inappropriate PPIs, discontinuing their chronic use can have long-term advantages. This may reduce the risk of experiencing side effects associated with prolonged PPI use and also save money.
In the short term, there is a possibility that discontinuation PPIs could result in a relapse of stomach symptoms. However, we expect a low probability of relapses or complications since only non-evidenced-based medications will be withdrawn and the best evidence-deprescribing guidelines will be followed to do that. Additionally, these patients will be closely monitored by both the pharmacist and the general practitioner to effectively manage any potential symptomatology that may arise.

Where is the study run from?
This study is taking place in primary care settings involving community pharmacies and Family Health Units in mainland Portugal.

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

Who is funding the study?
No specific funding has been obtained to undertake this trial. The Portuguese National Association of Pharmacies (ANF) sponsored this trial.

Who is the main contact?
Ms Sónia Romano (principal researcher, Ph.D. student)
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CSENIoR/1

Study information

Scientific Title
Effectiveness and cost-effectiveness of a Collaborative deprescribing intervention of Proton-pump-inhibitors on community-dwelling older adults: Protocol for the C-SENIoR, a pragmatic non-randomized controlled trial

Acronym
C-SENIoR

Study objectives
The intervention will reduce at least 20% the use of inappropriate proton-pump inhibitors among intervention participants compared with their counterparts

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 24/03/2021, Ethics Research Committee of NMS|FCM-UNL (CEFCM) (Campo Mártires da Pátria, 130, Lisboa, 1160-059, Portugal; +351 218 803 039; cefcm@nms.unl.pt), ref: 16/2021/CEFCM

2. approved 22/09/2022, Ethics Committee for Health from the Local Health Unit Alto Minho (Estrada de Santa Luzia, Viana do Castelo, 4901-858, Portugal; +351 258 802 108; comissao.etica@ulsam.min-saude.pt), ref: 50/2022/CES

Study design
Pragmatic multicentre non-randomized 2-arm controlled trial with a trial-based economic evaluation

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Overprescribing of proton-pump inhibitors

Interventions
The intervention is a collaborative care pathway, between community pharmacists and general practitioners aimed at deprescribing inappropriate PPI use and addressing other drug-related problems such as drug-drug interactions (DDIs). This patient-centered multifaceted intervention package consists of three main components:
1. Educational component provided by the pharmacist to the patient: The pharmacist assesses the appropriateness of PPI use based on the patient's self-reported clinical indication and the deprescription algorithm developed by the research team. The pharmacist then provides in-person oral and written educational information, including a booklet, regarding the rational use of medicines, indications and potential harms of chronic PPI use, benefits of deprescribing, potential withdrawal symptoms, and non-pharmacological strategies to alleviate symptoms. Additionally, a therapeutic profile of the patient's chronic medications, including relevant DDIs information, is compiled and shared with the general practitioner (GP).
2. Clinical assessment/deprescribing conducted by the GP: The GP contacts the patient, preferably by telephone, to discuss the appropriateness and strategy for PPI deprescribing, as well as to address any other medication-related issues. If the GP deems it necessary, a face-to-face appointment can be scheduled. Following the appointment, the clinical decisions are communicated to the pharmacist.
3. Patients' monitoring (symptoms and concerns): The community pharmacist conducts follow-up with the patients, assessing symptoms and addressing any questions. Telephone contact is made at 2 and 4 weeks after the GP appointment to evaluate potential symptom relapses and establish a symptom control strategy if needed. The 4-week telephone interview is conducted only for patients with indications for PPI dose reduction or withdrawal.
The comparator of the study is usual care.

Intervention Type
Mixed

Primary outcome(s)
Successful discontinuation or dose decrease of any PPIs, defined as a statistically significant reduction in medication use between the intervention and control groups at 3- and 6-month follow-up. Analysis of PPI use will be conducted using pharmacy medicine sales data linked to the patients' tax information number and confirmed through telephone interviews with the patients.

Key secondary outcome(s))
1. Patients' beliefs about PPI, measured by the Beliefs about Medicines Questionnaire (BMQ-specific) at baseline and 3-month follow-up.
2. Time until withdrawal since recruitment.

Other measurements at baseline and 6-month follow-up:
3. Number of long-term medications and proportion of patients on polypharmacy (patients with 5 or more medicines).
4. Health-related quality of life, assessed using the five-level version of the European Quality of

Life-5 Dimensions questionnaire (EQ-5D-5L instrument).
5. Self-reported adherence measured by the 7 items Measure Treatment Adherence questionnaire (MTA)
6. Number and degree of severity of DDIs identified by the dispensing software.
7. Adverse drug events, that is the absolute and relative counts of self-reported adverse drug events and type of events experienced by patients (e.g., needed professional support).
8. Healthcare resource utilization and costs (for the economic evaluation study)
9. For the intervention group - Satisfaction with the collaborative intervention (general and health professional related) is to be assessed only at the 6-month follow-up.

Process outcomes, such as the number of patients with a medical appointment and the number of pharmacist telephone follow-ups, will be collected ongoing to assess the fidelity and quality of the collaborative intervention

Completion date
15/06/2024

Eligibility

Key inclusion criteria
1. Community-dwelling older adults, aged 65 years old or over
2. Continuous use for more than 8 weeks of any PPI (ATC/WHO A02BC– esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)
3. Registered at the selected Family Health Units
4. Access to a telephone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Key exclusion criteria
1. Live in nursing homes or assisted-living facilities
2. Unable to communicate or speak in Portuguese
3. Have any cognitive impairment or any other condition that does not allow them to understand the study objectives or the questionnaire completion as perceived by the pharmacist.

Date of first enrolment
28/04/2023

Date of final enrolment
15/11/2023

Locations

Countries of recruitment
Portugal

Study participating centre
Community Pharmacies at Arcos de Valdevez Municipality
Arcos de Valdevez
Portugal
4970

Study participating centre
Community Pharmacies at Ponte da Barca Municipality
Ponte da Barca
Portugal
4980

Study participating centre
Family Health Unit Uarcos
Rua Eng. Adelino Amaro da Costa
Arcos de Valdevez
Portugal
4970-458 Arcos de Valdevez

Study participating centre
Family Health Unit Terra da Nóbrega
Rua Dr. Francisco Sá Carneiro, nº 2
Ponte da Barca
Portugal
4980-633 Ponte da Barca

Study participating centre
Centre for Health Evaluation and Reserach (CEFAR), National Association of Pharmacies
Rua Marechal saldanha 1
Lisbon
Portugal
1249-069

Sponsor information

Organisation
National Association of Pharmacies

Organisation
Unidade Local de Saúde do Alto MInho

Funder(s)

Funder type
Other

Funder Name
National Association of Pharmacies

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from the Centre for Health Evaluation & Research (CEFAR), Rua Marechal Saldanha 1, 1249-069 Lisboa, Portugal, cefar@anf.pt
Type of data: Patient-level data collected during the trial, after deidentification.
When will data be available (start and end dates): Beginning 12 months after the beginning of the study and 5 years following article publication
With whom: Researchers who provide a methodologically sound proposal
For what types of analyses: To achieve aims in the approved proposal and meta-analysis
By what mechanism will data be made available: Proposals should be directed to cefar@anf.pt. To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2025	04/11/2025	Yes	No
Protocol article		26/03/2024	27/03/2024	Yes	No
Participant information sheet			13/06/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes