

Multi-faceted intervention to improve antibiotic use in ambulatory care

Submission date 05/11/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/01/2021	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FMM-2008-FF

Study information

Scientific Title

Multi-faceted intervention to improve antibiotic use in ambulatory care: a cluster-randomised controlled trial

Acronym

INT-ATB-MED

Study objectives

Antibiotic resistance is one of the principal public health problems world-wide. Inappropriate use of antibiotics is currently regarded as the main determinant of such resistance.

Hypotheses:

1. The attitudes and knowledge towards antibiotics generate habits of prescription
2. The identification of the attitudes, knowledge and factors that generate habits of inadequate prescription will allow the design of specific educative interventions to improve the use of antibiotics
3. The intervention designed from gaps detected in knowledge and attitudes with respect to antibiotics and resistance will improve the prescription of antibiotics
4. The intervention will collaborate in the control of the bacterial resistance

Ethics approval required

Old ethics approval format

Ethics approval(s)

Spanish accredited Ethics Committee (Comité Ético de Investigación Clínica de Galicia), May 2007, ref: 2007/052

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied

Antibiotics prescriptions

Interventions

This is a cluster randomised controlled trial covering all general practitioners in a northwest region of Spain (Galicia). A specific educative intervention, designed from gaps detected in knowledge and attitudes with respect to antibiotics and resistance, will be carried out on the intervention group. The control group will not receive any specific intervention.

The intervention will consist of group outreach visits (40 minutes), and will be targeted at changing the knowledge-attitudes previously found to be associated with poor prescribing of antibiotics. An observational cohort study of a sample of 1500 primary care physicians will be carried out to identify knowledge-attitudes associated with inappropriate prescribing of antibiotics. The independent variables (knowledge-attitudes) will be assessed by a self-administered postal questionnaire and dependent variables are some quantity and quality indicators of the prescribing antibiotics.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Current primary outcome measure as of 06/09/2018:

Quality indicators for antibiotic prescribing drawn up by the European Surveillance of Antimicrobial Consumption Network (ESAC-Net), measured monthly from the last intervention to the end of study

Previous primary outcome measure:

Various quality indicators of the prescribing of antibiotics, assessed based on Infectious Diseases Clinical guidelines in Primary Care, measured monthly from the last intervention to the end of study

Secondary outcome measures

Various quantity indicators of the prescribing of antibiotics, measured monthly from the last intervention to the end of study.

Overall study start date

01/12/2011

Completion date

30/09/2013

Eligibility

Key inclusion criteria

1. General practitioners working during the period of the study
2. Aged approximately 30 - 60 years old, female or male

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

Estimated to include 3000 GPs (1500 at intervention group and 1500 at control group)

Total final enrolment

2610

Key exclusion criteria

General practitioners who work for private insurances during the period of the study

Added 06/09/2018:

Temporary staff and medical residents in training physicians exclusively assigned to emergencies

Date of first enrolment

02/12/2011

Date of final enrolment

30/09/2012

Locations

Countries of recruitment

Spain

Study participating centre

Departamento de Salud Pública

Santiago de Compostela

Spain

15782

Sponsor information

Organisation

The Foundation for Medical Research Mutua Madrileña (Fundación de Investigación Médica Mutua Madrileña) (Spain)

Sponsor details

C/Fortuny, 18

Madrid

Spain

28010

Sponsor type

Research organisation

Website

<http://www.mutua-mad.es/FundMM/jsp/Fhome.jsp>

Organisation

Instituto de Salud Carlos III

Sponsor details

C/ Sinesio Delgado, 4 (entrada por Avda. Monforte de Lemos, 5)

Madrid

Spain

28029

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oficina.informacion@isciii.es

Sponsor type

Research organisation

Website

<http://www.isciii.es/ISCIII/es/general/index.shtml>

Funder(s)

Funder type

Research organisation

Funder Name

The Foundation for Medical Research Mutua Madrileña (Fundación de Investigación Médica Mutua Madrileña) (Spain) - grant received

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

30/09/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date. The datasets include global antimicrobial prescriptions in the Health Care System of Galicia

(NHS). The data was provided by the NHS of Galicia, so their authorization is needed before sharing it.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/12/2020	26/01/2021	Yes	No