Educational interventions in pharmacists to improve antibiotic use

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17087

EU PAS number

EUPAS12881

Study ID

17087

DARWIN EU® study

No

Study countries

☐ Portugal

Study description

The aim of the study was to improve population antibiotic use through an educational intervention targeting community pharmacists attitudes and knowledge. it was conducted a cluster-randomized trial covering all community pharmacists in a region in the centre of Portugal.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Sciences Institute of Biomedicine, University of Aveiro

Portugal

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Institution **Educational Institution** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maria Teresa Herdeiro

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/01/2010

Actual: 01/05/2010

Study start date

Planned: 01/09/2010

Actual: 01/12/2010

Data analysis start date

Planned: 30/06/2013

Actual: 31/07/2013

Date of final study report

Planned: 31/07/2013

Actual: 31/10/2013

Sources of funding

- Other

More details on funding

FCT - Foundation for Science & Techonology

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Clinical trial

If ‘other’, further details on the scope of the study

Educational Intervention

Main study objective:

To reduce antibiotics consumption in the community.

Study Design

Clinical trial regulatory scope

Clinical trial not part of marketing authorisation application or subject to marketing authorisation approval

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Clinical trial randomisation

Randomised clinical trial

Clinical trial types

Cluster randomised trial

Single-arm trial

Population studied

Short description of the study population

All pharmacists working during the period study in the community pharmacies were included in this study.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

0

Study design details

Outcomes

Overall antibiotics consumption. Six main subclasses of antibiotic consumption (tetracyclines, penicillins, cephalosporins, sulfonamides and trimethoprim, macrocodes, quinolones).

Data analysis plan

It was used monthly sales data for each community sourced from IMS Health® (for the period May 2012 to September 2014) and aggregated by active substance in accordance with the Anatomical Therapeutic Chemical (ATC). To evaluate the impact of the intervention the data were expressed as number of packages per 1000 inhabitants per day (PID).

Documents

Study publications

Roque F, Soares S, Breitenfeld L, López-Durán A, Figueiras A, Herdeiro MT. Atti…

Roque F, Soares S, Breitenfeld L, Figueiras A, Herdeiro MT. Influence of commun…

Roque F, Herdeiro MT, Soares S, Teixeira Rodrigues A, Breitenfeld L, Figueiras …

Roque F, Soares S, Breitenfeld L, Gonzalez-Gonzalez C, Figueiras A, Herdeiro MT…

Roque F, Teixeira-Rodrigues A, Breitenfeld L, Piñeiro-Lamas M, Figueiras A, Her…

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

IMS Health - Portugal

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown