An open cluster-randomized, 18 month trial to compare the effectiveness of educational outreach visits with usual guideline dissemination to improve family physician prescribing (TEP (Trial Educational outreach Prescribing))

First published: 24/11/2013

Last updated: 02/07/2014

Study Ongoing

Administrative details

EU PAS number

EUPAS5149

Study ID

6992

DARWIN EU® study

No

Study countries

Portugal

Study description

Background: The Portuguese National Health Directorate has issued guidelines on prescription of anti-inflammatory drugs, acid suppressive therapy, and antiplatelets. However, their effectiveness in changing actual practice is unknown. Methods: The study will compare the effectiveness of educational outreach visits regarding the improvement of clinical guidelines compliance with usual dissemination strategies. A cost-benefit analysis will also be conducted. We will carry out a parallel, open, superiority, randomized trial directed to primary care physicians. Physicians will be recruited and allocated at a cluster-level (primary care unit) by minimization. Data will be analyzed at the physician level. Primary care units will be eligible if they use electronic prescribing and have at least four physicians willing to participate. Physicians in intervention units will be offered individual educational outreach visits (one for each guideline) at their workplace during a six months period. Physicians in the control group will be offered a single unrelated group training session. Primary outcomes will be the proportion of cyclooxygenase-2 inhibitors prescribed in the anti-inflammatory class, and the proportion of omeprazole in the proton pump inhibitors class at 18 months post-intervention. Prescription data will be collected from the regional pharmacy claims database. We estimated a sample size of 110 physicians in each group, corresponding to 19 clusters with a mean size of 6 physicians. Outcome collection and data analysis will be blinded to allocation, but due to the nature of the intervention physicians and detailers cannot be blinded.Discussion: This trial will attempt to address unresolved issues in the literature, namely, long term persistence of effect, the importance of sequential visits in an outreach program, and cost issues. If successful, this trial may be the cornerstone for deploying large scale educational outreach programs in Portugal.

Study status

Ongoing

Research institutions and networks

Institutions

Faculdade Ciências Médicas - Univ. Nova Lisboa

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Institution

Contact details

Study institution contact

Pedro Caetano giai@fcm.unl.pt

Study contact

giai@fcm.unl.pt

Primary lead investigator

Pedro Caetano

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/04/2012

Study start date
Planned: 29/11/2013

Actual: 01/01/2014

Data analysis start date
Planned: 30/06/2014

Actual: 30/06/2014

Date of final study report
Planned: 31/03/2016

Sources of funding

- Other

More details on funding

Ministério da Saúde, INSA, I.P.

Study protocol

Pinto An open cluster-randomized, 18 month trial.pdf (207.34 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Scope of the study:

Drug utilisation

Main study objective:

This trial aims to assess whether educational outreach visits are superior to usual implementation of guidelines regarding the reduction of inappropriate prescribing (compliance with prescription guidelines by family physicians). This for prescriptions of NSAIDs, Proton Pump Inhibitors, and anti platelets. The trial will also determine the cost-benefit of educational outreach visits.

Study Design

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

Medical condition to be studied

Gastrooesophageal reflux disease

Gastrointestinal disorder

Cardiovascular disorder

Pain

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

220

Study design details

Outcomes

Two primary outcomes at physician´s level: The proportion of COX-2 inhibitors (anatomical therapeutic classification ATC M01AH) prescribed within the entire NSAID class (ATC M01A) in defined daily doses 18 months after the intervention. The proportion of omeprazole (ATC A02BC01) within the entire proton pump inhibitors class (ATC A02BC) in defined daily doses 18 months after the intervention. There are seven secondary outcomes, also measured at the physician´s level: The proportion of COX-2 inhibitors within the NSAID class at 1 and 6 months, the proportion of omeprazole within the proton pump inhibitors class at 1 and 6 months, and the number of defined daily doses of clopidogrel prescribed per 1000 registered patients at 1, 6 and 18 months.

Data analysis plan

Researchers will have access to prescription data through a data monitoring system operated by the Lisbon (Portugal) Regional Health Administration. Data will be collected and provided by employees from this Administration according to researcher defined specifications. Importantly, researchers will not be directly involved in data collection. This information arrives with a two month delay from the date the prescription is dispensed. Data of prescribing physicians will be analyzed according to their randomly allocated group

regardless of adherence to the intervention (intention to treat analysis). Both groups will be compared on primary outcomes using generalized mixed-effects models. The ratio of COX-2 inhibitors to the entire NSAIDs class and the ratio of omeprazole to the entire proton pump inhibitors class and respective 95% confidence intervals will be calculated. Statistical significance will be assumed for a p-value less than 0.025.

Documents

Study, other information

Appendix 1.pdf (102.41 KB)

Study publications

Pinto D, Heleno B, Rodrigues DS, Papoila AL, Santos I, Caetano PA. An open clus...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

NoConflictsENCEPP.pdf (107.08 KB)

Composition of steering group and observers

CompositionSteeringGroupENCEPP.pdf (109.47 KB)

Signed code of conduct

2013-0022-Declaration CoC-SDPP-5149.pdf (885.31 KB)

Signed code of conduct checklist

2013-0022-Checklist CoC-SDPP-5149 (2).pdf (734.69 KB)

Signed checklist for study protocols

2013-0022-Checklist protocol-SDPP-5149 (2).pdf (197.5 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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

No