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An educational intervention to improve adverse drug reactions reporting among Galician physicians

Submission date 07/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2009	**Overall study status** Completed	
Last Edited 11/07/2019	**Condition category** Other	

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
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
An educational intervention to improve adverse drug reactions reporting: a cluster-randomised trial among Galician physicians

Study objectives
1. An educative intervention enhances the rate of reporting adverse drug reaction
2. An educative intervention enhances the quality of reporting, in terms of its relevance to the pharmacovigilance system
3. Duration of the effect in terms of quality and relevance could be more than one year

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Committee in Galicia gave approval on the 20th December 2007 (ref: 2007/410)

Study design
Cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Under-reporting of adverse drug reactions

Interventions
We implemented a continuing medical education multifaceted intervention comprising of a visit and report form. The main didactic material used for this purpose was a four-part presentation. The first part included definitions of pharmacovigilance and adverse drug reaction, a number of international studies on morbility and mortality, hospital admissions and the cost to health systems and patients, followed by the methods used in pharmacovigilance. During the second part, limitations of clinical trials for the detection of adverse drug reactions are explained as well as the advantages of the spontaneous reporting systems, explaining that under-reporting constituted the system's principal limitation. The third part was designed to change the five attitudes identified by a previous case-control study as being associated with under-reporting (complacency, insecurity, diffidence, indifference and ignorance). Another study carried out in

Galicia was also taken into account; in this last study four attitudes were identified: complacency, insecurity, diffidence and indifference. Then, emphasis was laid on the fact that only five minutes was required to complete the report form. Finally, it was explained how to report to the Galician Regional Pharmacovigilance Centre. The control group clusters received regular information provided by the Galician Regional Pharmacovigilance Centre but not the intervention.

Joint sponsor details:
Consellería de Sanidade e Servizo Galego de Saúde (Spain)
Edificio Administrativo de San Lázaro
15781 Santiago de Compostela
Spain

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rate of total notifications per month.

Secondary outcome measures
Rate of serious, unexpected, high-causality and new-drug-related adverse drug reactions per month.

Overall study start date
01/10/2007

Completion date
01/01/2011

Eligibility

Key inclusion criteria
All physicians working in the National Health System in Galicia (Spain)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
7498 physicians

Total final enrolment

7498

Key exclusion criteria
1. Not involved in clinical activities (e.g. analysis, administrative tasks, genetics, etc.)
2. Working in drug abuse rehabilitation centres
3. Working at the Regional Pharmacovigilance Centre or in any other unit that has a special programme for the reporting of adverse drug reactions

Date of first enrolment
01/10/2007

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Spain

Study participating centre
Facultad de Medicina
Santiago de Compostela
Spain
15782

Sponsor information

Organisation
Spanish Ministry of Health (Spain)

Sponsor details
Paseo del Prado 18
Madrid
Spain
28014

Sponsor type
Government

Website
http://www.msc.es

ROR
https://ror.org/00y6q9n79

Funder(s)

Funder type
Government

Funder Name
Collaboration agreement between the Spanish Ministry of Health (Spain) and the Galician Regional Government (Spain) for the promotion of safety practices in health care facilities

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015	11/07/2019	Yes	No