

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

Submission date 07/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/06/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/07/2019	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

Contact name

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Spain
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Additional identifiers

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

Study type(s)

Diagnostic

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 morbidity 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(s)

Rate of total notifications per month.

Key secondary outcome(s)

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

Completion date

01/01/2011

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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