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Improving adverse drug reaction reporting through workshops and telephone education in Portugal

Submission date	Recruitment status	[ ] Prospectively registered
10/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/09/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/09/2011	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Improving adverse drug reaction reporting through workshops and telephone education in Portugal: a cluster randomised trial

Study objectives
1. An educative intervention enhances the reporting rate of adverse drug reaction
2. An educative intervention enhances the quality of reporting, in terms of its relevance to the pharmacosurveillance 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)
1. Northern Region Health Authority (ARS-Norte) approved on 12/03/2007
2. The ethical committees of hospitals for intervention group approved on 27/05/2007 and 21/01/2008

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

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

Interventions
We implemented a continuing medical education multifaceted intervention comprising of telephone interviews and workshops.

Telephone education consisted of a telephone conversation between the researcher and the physician conducted according to the established guidelines and supported by material sent to the participant, including one acknowledge letter, one adverse drug reaction (ADR) spontaneous notification form and one Northern Pharmacosurveillance Unit (UFN) presentation folder.

The workshops consisted of a brief presentation including presentations of pharmacosurveillance and ADRs and its impact in the public health, description of the methods used in pharmacosurveillance and in spontaneous reporting system and the aptitudes and knowledges of physicians about ADR spontaneous reporting.

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
31/05/2009

Eligibility

Key inclusion criteria
All National Health System physicians working in the northern region of Portugal

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Physicians not involved in any clinical activity (e.g. engaged in administrative tasks, analysis, etc.)
2. Working in substance abuse and rehabilitation centres
3. Working at the regional pharmacosurveillance centre or any department having a specific voluntary adverse drug reaction reporting program and physicians attached to specific hospitals (cancer, maternity, etc)

Date of first enrolment
01/01/2007

Date of final enrolment
31/05/2009

Locations

Countries of recruitment
Portugal

Study participating centre
Unidade de Farmacovigilância do Norte
Porto

Portugal
4200

Sponsor information

Organisation
Northern Pharmacosurveillance Unit (Portugal)

Funder(s)

Funder type
Government

Funder Name
Ministry of Science, Technology and Superior Education (Portugal)- Science and Technology Fund (Fundação para a Ciência e Tecnologia) (grant SFRH/BPD/35746/2007)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration