

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

Submission date 10/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/09/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/09/2011	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

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 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

01/01/2007

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

Age group

Adult

Sex

Both

Target number of participants

6, 579 physicians

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)

Sponsor details

Unidade de Farmacovigilância do Norte

Faculdade de Medicina

Universidade do Porto

Porto

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ufn@med.up.pt

Sponsor type

Government

Website

<http://ufn.med.up.pt/>

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**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