A regional project to reduce adverse drug reactions due to medication errors in hospital

First published: 29/05/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5160

Study ID

27997

DARWIN EU® study

No

Study countries

Italy

Study description

Background: Medication errors are one of the most common types of medical error. A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient. Prescription errors account for 70% of medication errors that could potentially result in adverse drug effects. Objectives: A study has been projected to evaluate the incidence of adverse drug reactions (ADRs) due to medication errors in hospitalized patients before and after educational audits. Methods: All patients, aged ≥18 years, hospitalized in seven unit (three internal medicine and four geriatric) of the University Hospital of Verona during 3 months period (February- April 2013) were included in this study. The project was articled in 3 phases. In the first one, three monitors registered all ADRs occurred during hospital stay. Two panel of experts (6 physicians, 2 pharmacists and 2 pharmacologists) established, evaluating the available clinic information (e.g. clinical sheet) of all patients and according the Schumock and Thornton algorithm, if the ADRs were due to medication errors or not, in the case of error they identified the cause. At first the two panel worked separately, at a later stage a data condivision has been done to have shared data. In the second phase, educational audits directed to health care practitioners have been organized, and tools (e.g., check-list) to reduce the medication errors have been proposed. The third phase, that is similar to the first one and takes account of tools, is in progress. Preliminary Results: Preliminary data of the first phase showed that 1474 have been enrolled in the seven units involved, the analysis has been done for 1009 patients (68%) (median age: 76 years old with DS ± 15,2, female: 51%) who gave their informed consent. Three monitors registered 180 ADRs occurred in 1009 hospitalized patients, two panel evaluated 55 ADRs (30% of 180) as avoidable. Further results will be published as available.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy

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Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2011

Actual: 01/01/2011

Study start date
Planned: 04/02/2013

Actual: 04/02/2013

Data analysis start date
Planned: 03/06/2013

Actual: 03/06/2013

Date of final study report
Planned: 30/06/2014

Actual: 30/11/2016

Sources of funding

- Other

More details on funding

Italian Medicines Agency

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Medication Errors, Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The main objective of this study is to evaluate if educational audits organized in the second phase and directed to health care practitioners have reduced the medication errors due to adverse drug reaction in the third phase.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

All patients, aged ≥18 years, hospitalized in seven unit (three internal medicine and four geriatric) of the University Hospital of Verona during 3 months period (February- April 2013).

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

3.000

Study design details

Outcomes

All adverse drug reactions registered in all hospitalized patients during the study period and in the involved units

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Data analysis plan

A descriptive analysis will be conducted for all variables. The risk factors for ADRs and medication errors will be identified by studying the effects of age, the

sex, the duration of stay in the department and the severity of ADRs. The results will be expressed in terms of Odds Ratio (OR) with their 95% confidence intervals (95% CI). The level of significance will be estimated at 5%.

Documents

Study report

Drug Saf 2011_Pilot Study Med Errors.pdf (1.17 MB)

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.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown