Adverse drug reactions that lead to hospital admission in elderly patients

First published: 08/04/2015

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16807

EU PAS number

EUPAS9181

Study ID

16807

DARWIN EU® study

No

Study countries

☐ Spain

Study status

Finalised

Research institutions and networks

Institutions

Clinical Pharmacology Service, Bellvitge University Hospital/IDIBELL

Spain

First published: 30/04/2010

Last updated: 20/08/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Consuelo Pedrós

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2015

Actual: 01/04/2015

Study start date
Planned: 08/04/2015

Actual: 08/04/2015

Data analysis start date
Planned: 04/05/2015

Actual: 04/05/2015

Date of final study report
Planned: 01/07/2015

Actual: 01/07/2015

Sources of funding

- Other

More details on funding

No specific funding

Study protocol

Protocolo RAM-GER V01 01ABR15.pdf(67.54 KB)

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to assess the prevalence of ADR-related hospital admission in an elderly population.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Adverse drug reaction

Population studied

Short description of the study population

Elderly patients with adverse drug reactions (ADR)-related hospitalization.

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

1500

Study design details

Outcomes

The primary endpoint is urgent admission caused by an ADR in an elderly population. Hospitalization data, demographics data, drug exposure data, ADRs data, drug-reaction associations, number of emergency hospital admissions, number of in-hospital deaths

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Data analysis plan

A descriptive analysis of all variables will be performed in the overall sample and also in age subgroups (65-74 years, 75-84 years and >=85 years). The results will be expressed using absolute and relative frequencies. The chi-square test will be used for multiple comparisons, the Bonferroni method will be applied if necessary.The prevalence of ADR-related admission will be calculated by dividing the number of patients admitted for ADRs and the total number of admissions through the emergency room during the study period. The 95% CI for this estimate will be calculated.

Documents

Study publications

Pedrós C, Formiga F, Corbella X, Arnau JM. Adverse drug reactions leading to ur…

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

The Pharmacovigilance Programme of Bellvitge University Hospital collects cases of ADRs identified by a systematic daily review of admission diagnoses. Patients admitted with diagnoses included in a pre-defined list of diseases or syndromes potentially caused by drugs are identified. Their medical records are

reviewed by a clinical pharmacologist in order to assess causality.

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