Adverse drug reactions that lead to hospital admission in elderly patients

First published: 08/04/2015
Last updated: 29/03/2024

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 institution and networks

Institutions

Clinical Pharmacology Service, Bellvitge University Hospital/IDIBELL

Spain
First published: 30/04/2010
Last updated
25/06/2020

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

Contact details

Study institution contact
Consuelo Pedrós
Study contact

cpedros@bellvitgehospital.cat
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 data collection

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

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