Non-traumatic Haemorrhagic Adverse Events: A Cross-sectional Study in Emergency Departments (HARER)

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Study Finalised

Administrative details

EU PAS number

EUPAS28126

Study ID

28127

DARWIN EU® study

No

Study countries

Italy

Study description

Bleeding is a common clinical emergency that requires urgent medical attention. There is a general clinical interest in haemorrhages, which is increasing due to the recent introduction of new oral anti-coagulant drugs. Data about the incidence of bleeding in Emergency Room (ER) are lacking in literature, even if several studies report emergency admissions for haemorrhages associated with specific drugs or apparatuses. The retrospective observational study Haemorrhagic Adverse Reactions in Emergency Room (HARER) was designed in order to estimate the incidence of bleeding events and the incidence of suspected haemorrhagic adverse drug reactions as causes of Emergency Room visits. HARER takes into consideration the computerized medical records from two Emergency Departments of the University Hospital in Verona (Italy) from 2015 to 2016 over a twelve month period. According to a validated list available in literature, patients aged ≥ 18 years with an International Classification of Diseases, 9th Revision (ICD-9) diagnosis code at admission related to haemorrhage, but not caused by traumatic events, were included in the study. Unique identification code of the patient with a bleeding episode (as anonymization procedure), date of birth, gender, ICD-9 code, diagnosis at admission, complete patient’s medical history and outcome were recorded. Data were extrapolated from the First Aid database, which contains evaluation at admission, medical history, concomitant pharmacological treatment, descriptive discharge diagnosis, its corresponding ICD-9 CM code and outcome.Haemorrhages were classified into 5 groups: cerebral haemorrhage, gastrointestinal bleeding, epistaxis, haematuria and other haemorrhages.Drugs known to beassociated with haemorrhagic events were grouped into six categories:anticoagulants, antiplatelet drugs, heparins, SSRIs and NSAIDs, and we considered suspected haemorrhagic ADEs in all patient records reporting at least one of these drugs.

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

Study institution contact

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Study contact

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Primary lead investigator

Leone Roberto

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 09/12/2015

Actual: 09/12/2015

Study start date
Planned: 01/02/2016

Actual: 01/02/2016

Data analysis start date
Planned: 01/08/2016

Date of final study report
Planned: 01/08/2017

Actual: 06/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Our aims were to describe the incidence of haemorrhages and adversedrug events (ADEs) related to different classes of drugs as cause of ED admission, the characteristics of patients, the kind of bleeding and thedescription of hospitalizations and intra-hospital deaths.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Haemorrhagic disorder

Population studied

Short description of the study population

Adult patients(≥18 years).Cases were identified in 2 EDs of the Hospital ofVerona (population of about 300,000 inhabitants).All patients accessing from 1 February 2015 to 31 July 2015 and from 1 February 2016 to 31 July 2016,having an International Classification of Diseases, Clinical Modification code of discharge related to haemorrhage without concomitant diagnosis of trauma,were included

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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

118.000

Study design details

Outcomes

To estimate the incidence of hemorrhagic patients entering theemergency department during the study period

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Data analysis plan

To estimate the incidence of hemorrhagic patients entering theemergency department during the study period we calculated the ratiobetween the patients with an ICD-9 DM diagnosis that code for ahaemorrhage respect to all patients who entered in the same period.Descriptive baseline characteristics

were expressed in percentages andmeans ± standard deviation of the mean. Data about hemorrhage anddrugs are presented as percentage since they are categorical variables.

Documents

Study results

nontraumatic-haemorrhagic-adverse-events-a-crosssectional-study-inemergency-departments-2161-0495-1000377.pdf (393.57 KB)

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

Cross-sectional study. Data were extrapolated from the First Aid database

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