

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

**First published:** 14/02/2019

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS28126

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### Study ID

28127

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### DARWIN EU® study

No

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### Study countries

 Italy

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### 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  $\geq 18$  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 be associated 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.

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## **Study status**

Finalised

## Research institutions and networks

## Institutions

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

 Italy

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**Last updated:** 13/03/2025

**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

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**Study start date**

Planned: 01/02/2016

Actual: 01/02/2016

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**Data analysis start date**

Planned: 01/08/2016

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**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

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

Not applicable

## Methodological aspects

### Study type

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Our aims were to describe the incidence of haemorrhages and adverse drug events (ADEs) related to different classes of drugs as cause of ED admission, the characteristics of patients, the kind of bleeding and the description 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 ( $\geq 18$  years). Cases were identified in 2 EDs of the Hospital of Verona (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)
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## **Estimated number of subjects**

118000

# Study design details

## **Outcomes**

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

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## **Data analysis plan**

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

were expressed in percentages and means  $\pm$  standard deviation of the mean. Data about hemorrhage and drugs are presented as percentage since they are categorical variables.

## Documents

### Study results

[nontraumatic-haemorrhagic-adverse-events-a-crosssectional-study-in-emergency-departments-2161-0495-1000377.pdf](#) (393.57 KB)

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## 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](#)

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown