

# An observational study assessing the management of gastrointestinal and urogenital bleeding events in patients with atrial fibrillation treated with dabigatran etexilate (GI/GU bleeding management in AF patients using dab)

**First published:** 21/11/2013

**Last updated:** 30/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5214

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### Study ID

19556


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### DARWIN EU® study

No

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### Study countries

 Canada

 United States

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

 Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

Multiple centres: 44 centers are involved in the study

## Contact details

### Study institution contact

Dara Stein vaishali.patil@UBC.com

**Study contact**

vaishali.patil@UBC.com

## Primary lead investigator

Dara Stein

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 06/08/2012

Actual: 06/08/2012

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### Study start date

Planned: 10/01/2013

Actual: 21/01/2014

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### Data analysis start date

Planned: 23/06/2014

Actual: 30/09/2015

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### Date of final study report

Planned: 05/08/2014

Actual: 14/12/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

## 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 type list

##### **Study topic:**

Disease /health condition

Human medicinal product

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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

Disease epidemiology

Other

## **If 'other', further details on the scope of the study**

Disease Management

### **Data collection methods:**

Secondary use of data

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### **Main study objective:**

To assess the clinical characteristics of the GI and GU bleeding events in patients with AF taking dabigatran, and additionally to collect information describing the management to resolve those events and the clinical outcomes of these events.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Observational study based on a medical chart review

## Study drug and medical condition

### **Medicinal product name**

PRADAXA

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### **Medicinal product name, other**

Pradax

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## **Study drug International non-proprietary name (INN) or common name**

DABIGATRAN ETEXILATE

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### **Medical condition to be studied**

Atrial fibrillation

## **Population studied**

### **Short description of the study population**

Adult patients  $\geq 18$  years of age with confirmed diagnosis of non valvular atrial fibrillation (AF); documentation of presentation to an emergency departments/rooms (ED/ER) for an acute gastrointestinal (GI) and urogenital (GU) bleeding event (index event) between October 28, 2010 and August 21, 2013; and documentation that the index event occurred in a patient who reported having taken at least one dose of dabigatran within the 5 days prior to the index event.

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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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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with atrial fibrillation

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## Estimated number of subjects

220

## Study design details

### Outcomes

Frequencies of patients with index event safety outcomes  
(ongoing/resolved/deceased)Frequencies of patients receiving different type of  
interventions to stop the index eventFrequencies of bleeding types and  
anatomic locations of the index event

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### Data analysis plan

Descriptive statistics will be used to analyse the data by means of absolute and  
relative frequencies, means, standard deviations, medians, inter quartile  
ranges, minimum and maximum values, 95% confidence intervals and  
proportions, as appropriate.

## Documents

### Study results

[1160-162-study-report\\_redacted.pdf](#) (129.47 KB)

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Data management

ENCePP Seal

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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

Medical Chart review

## 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