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

Study ID

19556

DARWIN EU® study

No

Study countries

Canada

United States

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

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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

Study start date

Planned: 10/01/2013

Actual: 21/01/2014

Data analysis start date

Planned: 23/06/2014

Actual: 30/09/2015

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

Boehringer Ingelheim

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

Human medicinal product

Study type:

Non-interventional study

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

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

Non-interventional study design, other

Observational study based on a medical chart review

Study drug and medical condition

Name of medicine

PRADAXA

Name of medicine, other

Pradax

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

DABIGATRAN ETEXILATE

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Adult patients ≥ 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.

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)

Special population of interest

Other

Special population of interest, other

Patients with atrial fibrillation

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

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)

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

Medical Chart review

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