Evaluation of potential off-label use of dabigatran etexilate in Europe

First published: 08/10/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7591

Study ID

25630

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France
- [ ] United Kingdom

Study description

This is a descriptive, observational, multi-country European cross-sectional study of new users of dabigatran etexilate that aims to characterise on and off-label status and other medical characteristics at the time of the first captured prescription of dabigatran etexilate in each database. The study will be conducted using Cegedim Strategic Database (CSD, France), Danish National Databases (Denmark) and Clinical Practice Research Datalink (CPRD, UK).

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom
- ☐ United Kingdom (Northern Ireland)
- ☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution **Not-for-profit** **ENCePP partner**

CSD Medical Research (CSDMR)

France

First published: 18/07/2012

Last updated: 20/08/2024

Institution | Other

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

Pharmacoepi center, University of Southern Denmark

Denmark

First published: 22/04/2010

Last updated: 27/07/2023

Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Manel Pladevall-Vila

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/11/2013

Study start date

Planned: 03/11/2014

Actual: 28/11/2014

Date of final study report

Planned: 30/11/2016

Actual: 15/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim GmbH

Study protocol

1160-144--protocol-revision-04_redacted.pdf (1.66 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Estimate the proportion of off-label use in new users of dabigatran according to the recorded clinical indication or generated proxies as available in each DB.Describe the characteristics of new users of dabigatran including dose, demographics, clinical indication, morbidity and use of other medications prior to the first captured prescription, stratified by usage sub-group—on- or off-label use.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

DABIGATRAN ETEXILATE

Population studied

Short description of the study population

Patients who received a new prescription of dabigatran etexilate in the study period and have at least 1 year of enrolment in the electronic database and have not been prescribed dabigatran etexilate during the 1-year period prior to the index date.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

Renal impaired

Estimated number of subjects

15000

Study design details

Outcomes

The main outcome of this study is the proportion of off-label use estimated among new users of dabigatran etexilate, new users will be characterised.

Data analysis plan

The analyses will be descriptive at baseline. The main analysis will be to estimate (with 95% confidence intervals) the prevalence proportion of off-label use among new users of dabigatran etexilate during the overall study period in each of the study populations. All the results will be presented for each country-specific database. A weighted, pooled prevalence of off-label use among new

users of dabigatran etexilate for the entire study population (study populations of the CPRD, Cegedim, and Danish national databases combined) will be estimated (with 95% confidence intervals) when the individual results of all three databases are available.

Documents

Study results

nis-existing-data-report-text-part-0303644-bi-dabigatran_redacted.pdf (182.25 KB)

Study publications

Cainzos-Achirica M, Varas-Lorenzo C, Pottegård A, Asmar J, Plana E, Rasmussen L...

Cainzos-Achirica M, Varas-Lorenzo C, Pottegård A, Asmar J, Plana E, Rasmussen L...

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 source(s)

Clinical Practice Research Datalink

Data source(s), other

Cegedim Strategic Data – Longitudinal Patient Database France

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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