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

PURI
https://redirect.ema.europa.eu/resource/25630

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 institution 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 19/02/2024

Institution | ENCePP partner | Not-for-profit

CSD Medical Research (CSDMR)

France
First published: 18/07/2012
Last updated 13/09/2012

Institution | ENCePP partner | Other

Clinical Practice Research Datalink (CPRD)

United Kingdom
First published: 15/03/2010
Last updated 02/07/2019

Institution | ENCePP partner | Laboratory/Research/Testing facility

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 data collection

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

Data sources

Data source(s)
Clinical Practice Research Datalink

Data source(s), other
Cegedim Strategic Data – Longitudinal Patient Database France

Data sources (types)
Administrative data (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