Surveys among Health Care Professionals and Patients to assess their knowledge and behaviour with respect to the new (2018) Risk Minimization Measures for valproate use in Europe. (VALNAC09348)

First published: 28/04/2020

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS34465

Study ID

34466

DARWIN EU® study

No

Study countries

France

Germany

Poland

Spain

Sweden

United Kingdom

Study description

This survey aims to measure the awareness, knowledge and behaviour of prescribing physicians, gynaecologists and pharmacists with respect to the new (2018) RMMs for valproate, as well as of patients treated with valproate in France, Germany, Poland, Sweden, Spain and UK. The new RMMs include new prescribing and dispensing conditions, Pregnancy Prevention Program (PPP), educational materials (EM) i.e. Healthcare Professionals (HCPs) guide, Patient Card, Patient Guide, and Annual Risk Acknowledgement form. Objectives for HCPs - To assess HCPs awareness related to both receipt and reading of the new (2018) RMMs including direct healthcare professional communication (DHPC) and educational materials (EMs) for valproate-containing medicines. - To assess HCPs knowledge with respect to the new (2018) RMMs including measures of PPP, prescribing/dispensing conditions and risks associated with exposure to valproate-containing medicines during pregnancy. - To assess HCPs behaviour with respect to the new (2018) RMMs regarding the measures of the PPP. Objectives for Patients - To assess the awareness of women of child bearing potential (WCBP) treated with valproate-containing medicines related to both receipt and reading of the new (2018) RMMs including the educational materials provided by the HCPs. - To assess the knowledge of WCBP treated with valproate-containing medicines with regards to risks associated with use of valproate-containing medicines during pregnancy and measures to avoid exposed pregnancies. - To assess the behaviour of WCBP treated with valproate-containing medicines with respect to the new (2018) RMMs including measures of the PPP. Data collection Mainly web questionnaire, paper version proposed to patients, pharmacists not be surveyed in France. Sample size: -

1328 completed questionnaires from physicians who have prescribed valproate, 215 from gynaecologists having seen patients treated with valproate, - 384 completed questinnaires

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Florent Richy

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 16/10/2018

Study start date
Planned: 01/06/2020

Actual: 01/12/2020

Date of final study report
Planned: 01/02/2021

Actual: 28/07/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

A Consortium of Marketing Authorization Holders for valproate and related substances

Study protocol

VALNAC09348 HCP Patients Surveys Protocol V6.0 04NOV2020 clean.pdf
(874.03 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/A-31/1454

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

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate awareness, knowledge and behaviour of Health Care Professionals and Patients with respect to the new (2018) Risk Minimization Measures for valproate use in 6 European countries.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Multinational survey

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AG01) valproic acid

valproic acid

(N03AG02) valpromide

valpromide

Medical condition to be studied

Epilepsy

Bipolar disorder

Pregnancy

Population studied

Short description of the study population

The study focused on female patients of childbearing age received treatment with valproate-containing medicines.

Inclusion criteria:

Prescribers of valproate: GPs, neurologists (including pediatric neurologists), paediatricians and psychiatrists who prescribed valproate containing medicines to female patients of childbearing potential in the last 6 months.

Gynaecologists: Gynaecologists who have had a consultation with at least one female patient of childbearing potential treated with valproate containing medicines in the last 6 months.

Pharmacists: Pharmacists who have dispensed valproate containing medicines to female patients of childbearing potential in the last 6 months. The survey will enrol only those pharmacists who have dispensed the drug in a pre-specified period of last six months.

Patients

• Female patients of childbearing age (i.e., 13 to 49 years of age) and being treated with valproate-containing medicines at the time of the survey

• Who consent to participate in this self-administered survey (for patients between 13 to 17 years of age, the survey shall be filled out by their parent, guardian or caregiver)

Exclusion criteria:

• HCPs or patients who may have conflicts of interest with the survey (i.e. patients employed by regulatory bodies or pharmaceutical companies).

• HCPs or patients (with a relative) involved in valproate-related lawsuits or associations for victims of valproate syndrome.

Age groups

- 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

Pregnant women

Estimated number of subjects

2.695

Study design details

Data analysis plan

All the analyses will be descriptive. Continuous variables will be described by their mean, standard deviation, and median, first quantile (Q1), third quantile (Q3), minimum and maximum. Categorical variables will be described as total number and relative percentage per category. Analysis for the survey will be performed for patients and HCPs (prescribers, gynaecologists and pharmacists) separately for the endpoints described below, and will include the total number of patients and HCPs with valid responses to all relevant questions and the percentage of patients and HCPs with a positive response for the questions. The statistical results of the included European countries will be presented overall and then at country level. The analysis of the Patients' and HCPs' surveys will then be broken down by subpopulation of interest, i.e. according to therapeutic indication (epilepsy / bipolar disorders).

Documents

Study results

epi-valproate-VALNAC09348-PASS-Surveys-Abstract-Final-Study-Report-v1.0-sept2023.pdf (140.47 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

The recruitment of Physicians will be conducted using OneKey database, which provides the lists and contact details of healthcare providers. The recruitment of Pharmacist will be conducted according to a representative panel following a randomized sampling plan for the whole pharmacist population for each country. Patients will be recruited by HCPs from OneKey and a consumer panel.

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

No