Effectiveness of the Additional Risk Minimization Measures in Conveying Safety Information to HCPs Dispensing, Administering or Prescribing Fosphenytoin

First published: 27/12/2018

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS27343

Study ID

34474

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Sweden
- ☐ United Kingdom

Study description

The overall objective is to evaluate the effectiveness of the additional RMMs being implemented across Europe to mitigate the risks of medication errors and off-label use in children under 5 years of age with the use fosphenytoin.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kofi Asomaning

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/06/2018

Actual: 19/06/2018

Study start date
Planned: 10/01/2019

Actual: 25/02/2019

Date of final study report
Planned: 04/09/2019

Actual: 25/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

FOSPHENYTOIN_DRAFT PROTOCOL VS5 FINAL VS4.pdf (866.59 KB)

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)

Other study registration identification numbers and links

A9821002

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Effectiveness of Risk Minimization Measures

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Descriptive survey

Data collection methods:

Primary data collection

Main study objective:

The overall objective is to evaluate the effectiveness of the additional RMMs being implemented across Europe to mitigate the risks of medication errors and off-label use in children under 5 years of age with the use fosphenytoin.

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

Healthcare professionals (HCPs) who have prescribed, prepared or administered fosphenytoin across the study countries (UK, Sweden and France).

The survey was conducted among HCPs meeting the following inclusion criteria:
• HCPs with experience prior to the survey administration of prescribing/preparing/administering at least one dose of fosphenytoin
• Willing/consent to participate in this self-administered survey

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Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

200

Study design details

Data analysis plan

The proportions of correct and appropriate answers to selected questions asked in the questionnaire will be provided among HCPs who provided answers to those questions. Depending on the sample size, the endpoints will be assessed overall, by country and among subgroups of HCPs (physician vs. nurse vs. pharmacist).

Documents

Study results

A9821002_FOSPHENYTOIN FINAL STUDY REPORT_V1_25 NOV 2019_EU PAS REGISTER.pdf (842.63 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

Survey of healthcare practioners

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