VERIFIE (Velphoro Evaluation of Real-lIfe saFety, effectIveness and adherencE): Non-interventional study to investigate the short- and long-term real-life safety, effectiveness, and adherence of Velphoro in patients with hyperphosphataemia undergoing haemodialysis or peritoneal dialysis

First published: 23/12/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11502

Study ID

35019

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

The new oral highly potent P binder Velphoro is a mixture of polynuclear iron(III)-oxyhydroxide, sucrose, and starches. It was well tolerated in the clinical development program. Velphoro has been approved by the European Medicines Agency (EMA) (August 2014). The approved indication in the European Union (EU) is to control sP levels in adult CKD patients on HD or PD. Experience to date in the use of Velphoro results from more than 1,100 patients who have participated in clinical trials. During clinical trials, the most common side effects included gastrointestinal (GI) disorders (mostly diarrhoea and stool discolouration) and abnormal product taste. The majority of GI disorders occurred early during treatment and receded with continued drug application.It is of major interest to observe the drug in daily use outside of controlled trial Settings. The Marketing Authorisation Holder wishes to obtain further systematic data within this non-interventional study to investigate short and long-term (beyond 1 year) safety, including GI effects, potential masking of GI bleedings due to stool discolouration, and the risk of iron accumulation. Evaluation of PD patients is of special interest, since their numbers have been limited within the clinical trials.Furthermore, effectiveness and treatment adherence during real-life use will be evaluated.

Study status

Finalised

Research institutions and networks

Institutions

Vifor Fresenius Medical Care Renal Pharma France

Multiple centres: 178 centres are involved in the study

Contact details

Study institution contact

Manuela Stauss-Grabo Manuela.Stauss-Grabo@fmc-ag.com

Study contact

Manuela.Stauss-Grabo@fmc-ag.com

Primary lead investigator

Manuela Stauss-Grabo

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/09/2015

Actual: 30/09/2015

Study start date
Planned: 29/01/2016

Actual: 06/04/2016

Data analysis start date
Planned: 06/04/2019

Actual: 14/06/2019

Date of interim report, if expected
Planned: 26/07/2018

Actual: 26/07/2018

Date of final study report
Planned: 31/12/2019

Actual: 16/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Vifor Fresenius Medical Care Renal Pharma France

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The MAH wishes to obtain further systematic data within this non-interventional study to investigate short and long-term (beyond 1 year) safety, including GI effects, potential masking of GI bleedings due to stool discolouration, and the risk of iron accumulation. Evaluation of PD patients is of special interest, since their numbers have been limited within the clinical trials.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VELPHORO

Medical condition to be studied

Hyperphosphataemia

Population studied

Short description of the study population

Patients with hyperphosphataemia undergoing haemodialysis or peritoneal dialysis.

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

Renal impaired

Estimated number of subjects

1400

Study design details

Outcomes

• To evaluate short and long-term (beyond 1 year) safety and tolerability of Velphoro in general in HD and PD patients.• To specifically assess the potential risk of iron accumulation of Velphoro in HD and PD patients.• To investigate the potential masking of GI bleedings in patients treated with Velphoro in HD and PD patients. • To evaluate the effectiveness of Velphoro in routine clinical practice.• To evaluate the adherence to Velphoro therapy.

Data analysis plan

Statistical analyses will be of an exploratory and descriptive nature. All variables will be analysed descriptively with appropriate statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by descriptive statistics (i.e. number of patients (n), mean, standard deviation, minimum, median, quartiles, and maximum). Continuous variables will be summarised by absolute value and changes from baseline per analysis time point, if applicable.All analyses will be performed for the total study population (overall analysis). In addition, data will be stratified

by type of dialysis treatment (HD or PD respectively) and by duration of Velphoro treatment. Whenever reasonable and dependent on the number of patients in each specific subgroup, data will be stratified by further parameters.The sample size and disposition information by analysis time point will be displayed in a frequency table.

Documents

Study results

2019-12-10_CLMD_VPH_VERIFIE_Final_Report_Synopsis_Redacted.pdf (175.92 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

Prospective patient-based data collection, Medical records, routine measurements and assessments (e.g. laboratory parameters), patients questionnaires.

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