Retrospective drug utilisation study to investigate the routine use of hydroxyethyl starch (HES)-containing infusion solutions of B. Braun Melsungen AG in hospitals

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Study Finalised

Administrative details

EU PAS number

EUPAS12540

Study ID

38989

DARWIN EU® study

No

Study countries

Belgium

Czechia

France

Germany
Italy
Netherlands
Poland
Spain
Sweden

Study description

The objective of the Drug Utilisation Study (DUS) is to assess the adherence of hospital physicians to the revised European Product Information (PI) Summary of Product Characteristics (SmPC), Package Leaflet for Hydroxyethyl Starch (HES) - containing medicinal products of B. Braun Melsungen AG concerning indication, posology (dosage) and contraindications.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 40 centres are involved in the study

Contact details

Study institution contact

Scientific Contact dus-hes130-encepp@bbraun.com

Study contact

dus-hes130-encepp@bbraun.com

Primary lead investigator

NA NA

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/09/2015

Actual: 14/09/2015

Study start date

Planned: 01/03/2016

Actual: 01/03/2016

Data analysis start date

Planned: 28/02/2017

Actual: 28/02/2017

Date of final study report

Planned: 06/11/2017

Actual: 22/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

B.Braun Melsungen AG

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)

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:

The objective of the DUS is to assess the adherence of hospital physicians to the revised European PI for HES-containing medicinal products of B. Braun Melsungen AG concerning indication, posology (dosage) and contraindications.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, non-interventional, multinational, multi-centre study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B05AA07) hydroxyethylstarch

hydroxyethylstarch

Population studied

Short description of the study population

Hospital physicians in Belgium, Czech Republic, France, Germany, Italy, Netherlands, Poland, Spain and Sweden using any hydroxyethyl starch (HES)

products of B. Braun Melsungen AG.

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)

Estimated number of subjects

3.000

Study design details

Outcomes

Outcome measure is the adherence to the concerned sections of the revised European PI. Usage of these medicinal products according to indications, posology (dosage), and contraindications as specified in the revised PI of the HES solutions will be assessed.

Data analysis plan

Because of the exploratory character of this study only descriptive statistics will be performed. All parameters will be presented as mean +/- standard deviation for continuous normally distributed variables and median (25th, 75th percentile) for ordinal and continuous non-normal (skewed) variables.

Categorical variables will be presented as percentage (and 95 % confidence interval). All analyses will be performed for the overall population as well as for each country separately. All data will be examined for the overall population and subgroups (each site/country separately) specified by indication and contraindications according to the revised PI.

Documents

Study results

PASS FSR-BBraun-BBEH1408-HC1408-Abstract_blackened.pdf (162.3 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

Retrospective non-interventional patient chart study

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