Retrospective Drug Utilisation Study to investigate the routine use of Hydroxyethyl Starch (HES)- containing Infusion Solutions in Hospital (NA)

First published: 09/09/2015

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10897

Study ID

24380

DARWIN EU® study

No

Study countries

Austria

Belgium

Czechia

France
Germany
Hungary
Netherlands
Poland
Spain

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 concerning indication, posology (dosage) and contraindications.

Study status

Finalised

Research institutions and networks

Institutions

Kantar Health

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Institution

Multiple centres: 45 centres are involved in the study

Contact details

Study institution contact

Scientific Contact HES-DUS_ENCePP-enquiry@fresenius-kabi.com

Study contact

HES-DUS_ENCePP-enquiry@fresenius-kabi.com

Primary lead investigator

Mercedes Apecechea

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2015

Actual: 09/12/2015

Study start date

Planned: 01/10/2015

Actual: 18/05/2016

Data analysis start date
Planned: 01/10/2016

Actual: 05/12/2016

Date of final study report
Planned: 31/03/2017

Actual: 06/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Fresenius Kabi Deutschland GmbH

Study protocol

HE06-022PW-CNI-HESDUS_CSP blackened_all.pdf (7.02 MB)

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 medicina! products concerning indication, posology (dosage), and contraindications.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B05AA07) hydroxyethylstarch

hydroxyethylstarch

Population studied

Short description of the study population

Patients who were receiving any of the hydroxyethyl starch-containing medicinal products within the predefined timeframe in Belgium, Czech Republic,

France, Germany, Netherlands, Poland, Spain, Sweden, United Kingdom.

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

3000

Study design details

Outcomes

Outcome measure is the adherence to the concerned sections of therevised European PI for HES-containing medicinal products. Usage of these medicinal products according to indications, posolagy (dosage), and contraindications as specified in the revised PI ofthe 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. Ail data will be examined for the overall population and subgroups (each site/country separately) specified by indication andcontraindications according to the revised PI.

Documents

Study results

HE06-022-CNI-HESDUSCSR-Abstract-gesch.pdf (2.82 MB)

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 (based on medical records)

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