Retrospective, Multinational, Drug Utilisation Study (DUS) to Investigate the Routine Use of Hydroxyethyl Starch (HES)-containing Infusion Solutions in HES-Accredited European (EU) Hospitals after Implementation of a Set of Risk Minimisation Measures (HE06-027-CNI)

First published: 20/11/2019

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS32145

Study ID

46150

DARWIN EU® study

No

Study countries

Belgium
France
Germany
Hungary
Italy
Netherlands
Poland
Spain

Study description

The primary objective of the imposed DUS is to assess the non-adherence of physicians in HES-accredited hospitals to the approved European Product Information regarding indication for use, contraindications and posology (dosage) for HES 130-containing medicinal products in clinical routine after implementation of a set of risk minimisation measures. This allows to evaluate the effectiveness of these measures.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 40 centres are involved in the study

Contact details

Study institution contact

Contact Scientific HES-DUS2_ENCePP-enquiry@fresenius-kabi.com

Study contact

HES-DUS2_ENCePP-enquiry@fresenius-kabi.com

Primary lead investigator

Elena Bousiaki

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/04/2019

Study start date

Planned: 12/02/2020

Actual: 19/02/2020

Data analysis start date

Actual: 16/11/2020

Date of final study report

Planned: 16/07/2020

Actual: 06/07/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Fresenius Kabi Deutschland GmbH, B. Braun Melsungen AG

Study protocol

EU-HES-DUS-HE06-027-CNI-CSP-Final_v2.0.pdf (533.31 KB)

EU-HES-DUS-HE06-027-CNI-CSP-v4.0-Abstract-for-ENCePP.pdf (179.79 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)

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 primary objective of the imposed DUS is to assess the non-adherence of physicians in HES-accredited hospitals to the approved European Product Information regarding indication for use, contraindications and posology (dosage) for HES 130-containing medicinal products in clinical routine after implementation of a set of risk minimisation measures.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, non-interventional, multinational, European study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B05AA07) hydroxyethylstarch

hydroxyethylstarch

Population studied

Short description of the study population

The source population includes all patients fulfilling the inclusion and none of the exclusion criteria.

Inclusion Criteria

• Patients who received any of the HES 130 solutions listed in Annex 1a/1b after implementation of a set of risk minimisation measures at the respective HES-accredited hospital in the documentation period.

Exclusion Criteria

• Patients who participated in interventional clinical trials investigating HES up to 3 months prior to or during the recorded HES infusions(s)

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

1749

Study design details

Outcomes

Outcome measure is the number and proportion of patients whose treatment during the hospital stay did not adhere to the approved European PIs regarding indication, contraindications and dosage (posology). Analysis of non-adherence to one or more specifications made in the approved European PIs (concerning the indication, contraindications and dosage posology) will also be conducted for each single HES 130 prescription as statistical unit for assessment (instead of considering the patient as statistical unit) and will be presented as secondary measure.

Data analysis plan

Due to the exploratory character of this study only descriptive statistics will be used for the analysis of the study variables. For continuous variables, mean ± standard deviation, median and quartile (25th, 75th percentile) and numbers of non-missing and missing values will be presented. For categorical variables, frequencies and percentage will be shown for each category and for missing values. All data will be examined for the overall population and subgroups (each country/ age group/ hospital type/hospital ward separately) specified by indication and contraindications according to the revised PI. The number and percentage of patients who received HES 130 and were documented as non-adherent to one or more of the specifications made in the PIs (concerning the indication, contraindications and dosage) will be evaluated for the overall patient population and will be displayed together with 95 % confidence intervals for the percentage.

Documents

Study results

HE06-027-CNI-CSR-v2.0-Abstract-for-ENCePP.pdf (129.25 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 (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

No