Hydroxyethyl starch (HES) solutions and risk of acute kidney injury and mortality in acute trauma patients

First published: 28/10/2019

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS31996

Study ID

31997

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A systematic review of the literature was performed, to update the previously systematized evidence in 2013, regarding the risk of using HES in trauma patients. Only the new evidence occurred since the last referral (when all available evidence was thoroughly reviewed) was considered (01/08/2013 - 22/11/2017).

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alexandra Pacurariu

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2017

Actual: 01/09/2017

Study start date
Planned: 15/09/2017

Actual: 15/09/2017

Data analysis start date
Planned: 01/11/2017

Actual: 01/11/2017

Date of final study report
Planned: 27/11/2017

Actual: 27/11/2017

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

A systematic review, to update the existing evidence regarding HES association with acute kidney injury and mortality in acute trauma patients.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

HYDROXYETHYL STARCH 130/0.4

Medical condition to be studied

Death

Acute kidney injury

Population studied

Short description of the study population

Acute trauma patients who had received hydroxyethyl starch (HES) solutions.

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

Other

Special population of interest, other

Acute trauma patients

Estimated number of subjects

0

Study design details

Outcomes

Acute kidney injuryAll-cause mortality

Data analysis plan

A systematic review of literature was performed. Searches in PubMed and Embase were conducted, for English language articles, studies conducted in humans, published between 01/08/2013 and 22/11/2017. The following exclusion criteria were applied: - preclinical studies - case studies or case series- reviews, commentaries or opinion letters - clinical guidances, opinion papers, recommendationsData collection in individual studies was required to go beyond 2013 and for meta-analysis - to include studies finalized after October 2013.The studies were reviewed only at abstract level.

Documents

Study results

Hydroxyethylstarch -lit review-24NOv 2017.pdf (258.57 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)

Published literature

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