A before and after, cross-sectional survey to evaluate the effectiveness of risk minimisation measures to minimise the risk of hospital-acquired hyponatraemia

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Study Ongoing

Administrative details

EU PAS number

EUPAS38732

Study ID

38733

DARWIN EU® study

No

Study countries

Denmark

Study description

In July 2017, the European Pharmacovigilance Risk Assessment Committee concluded that there is an increased risk of hospital-acquired hyponatraemia associated with the administration of hypotonic intravenous fluids containing electrolytes and/or carbohydrates. Besides updating the product information, it was decided that further risk minimisation measures should be initiated at the national level. The Danish Medicines Agency and the Danish Patient Safety Authority Agency decided to distribute a treatment guide in June 2020 with basic information on treatment and prevention of hyponatraemia to all physicians working at emergency departments in Denmark. The primary objective of this study was to evaluate the effectiveness of the treatment guide implemented as part risk minimisation measures to reduce the risk of hospital-acquired hyponatraemia by assessing prescribing practice before and after the introduction of the treatment guide.

Study status

Ongoing

Research institutions and networks

Institutions

Data Analytic Center (DAC), Danish Medicine Agency

Denmark

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Institution | EU Institution/Body/Agency | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Per Sindahl

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/09/2018

Actual: 04/09/2018

Study start date

Planned: 01/03/2019

Actual: 01/03/2019

Date of final study report

Planned: 01/12/2021

Sources of funding

- Other

More details on funding

Danish Medicines Agency

Regulatory

Was the study required by a regulatory body?

No

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

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study was to evaluate the effectiveness of a treatment guide implemented as part of a risk minimisation measure to reduce the risk of hospital-acquired hyponatraemia by assessing prescribing practice before and after the introduction of the treatment guide.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B05BA03) carbohydrates

carbohydrates

(B05BB02) electrolytes with carbohydrates

electrolytes with carbohydrates

(B05BB01) electrolytes

electrolytes

Medical condition to be studied

Hyponatraemia

Population studied

Short description of the study population

The study population consisted of the target audience of the treatment guide, that is, all physicians working in Danish emergency departments. There are 38 emergency departments in Denmark distributed over 21 hospitals, and 348 physicians work in emergency departments in Denmark based on the estimated source population from 2014. We focused on emergency departments because IV fluid prescriptions are initiated in the emergency department, and previous research has shown that errors in the prescription of IV fluids are particularly likely in emergency departments.

Age groups

- 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

200

Study design details

Outcomes

Prescribing practice measured as the selection of hypotonic fluids, • Knowledge about hyponatraemia and IV fluids • Process indicators • Usefulness of the treatment guide

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Data analysis plan

Statistical analyses were mainly descriptive. Each question was evaluated individually and described by frequency and percentage. Summary measures were calculated for all scenario questions (n=4), all knowledge questions (n=8) and all scenario and knowledge questions combined. Confidence intervals (95% CI) were calculated for all before and after comparisons. A priori we defined an absolute success criterion as a risk of being treated with hypotonic fluids of no more than 10% in each scenario. Relative risk reduction of being treated with hypotonic fluids was used as a measure of the effectiveness of the risk minimisation measure. Univariate logistic regression was used to explore the predictors of prescribing practice.

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

The survey was a primary data collection using a self-administered questionnaire conducted through a combination of paper and web 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