Renal replacement therapy: The influence of citrate vs. acetate buffering component on indoxyl sulfate elimination during bicarbonate dialysis

First published: 25/04/2018

Last updated: 25/04/2018

Study Planned

Administrative details

EU PAS number

EUPAS23714

Study ID

23715

DARWIN EU® study

No

Study countries

☐ Czechia

Study description

A monocentric, prospective, open cohort study will be performed in 43 male patients from a single hemodialysis center undergoing chronic renal replacement therapy. The aim is to determine the influence of acetate vs. citrate buffered dialysis fluids in hemodialysis (HD) and post-dilution hemodiafiltration (HDF) settings on the elimination of indoxyl sulfate. Also, additional factors potentially influencing the serum concentration of indoxyl sulfate will be evaluated.

Study status

Planned

Research institutions and networks

Institutions

University Hospital Hradec Králové

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department of Clinical Biochemistry

Contact details

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Primary lead investigator

Radomir Hyspler

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/05/2017

Actual: 02/05/2017

Study start date

Planned: 01/09/2017

Date of final study report

Planned: 02/07/2018

Sources of funding

- Other

More details on funding

Ministry of Health of the Czech Republic grant DRO

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The aim of this study was to determine the influence of acetate vs. citrate buffered dialysis fluids in hemodialysis (HD) and post-dilution hemodiafiltration (HDF) settings on the elimination of indoxyl sulfate.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Additional medical condition(s)

Renal replacement therapy

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Special population of interest

Renal impaired

Estimated number of subjects

45

Study design details

Outcomes

Elimination of indoxyl sulfate estimated from its serum concentrations.

Data analysis plan

All statistical analyses will be performed using the SigmaStat software version 3.1. (Systat Software Inc. US).

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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