

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

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Study

Planned

## Administrative details

### EU PAS number

EUPAS23714

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### Study ID

23715

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### DARWIN EU® study

No

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### Study countries

 Czechia

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### 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.

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## Study status

Planned

## Research institutions and networks

### Institutions

[University Hospital Hradec Králové](#)

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Institution

[Department of Clinical Biochemistry](#)

## Contact details

### Study institution contact

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Study contact

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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

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**Study start date**

Planned: 01/09/2017

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**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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **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)

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**Special population of interest**

Renal impaired

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**Estimated number of subjects**

45

## Study design details

**Outcomes**

Elimination of indoxyl sulfate estimated from its serum concentrations.

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**Data analysis plan**

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

## 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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No