

# A Multicenter, Non-interventional, Observational, Post-Approval Safety Study of Updated ACCUSOL 35 Solutions in Continuous Renal Replacement Therapy (ACCUPASS)

**First published:** 25/06/2014

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6800

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### Study ID

29084

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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## Study description

This is a multicenter, non-interventional, single-arm, observational, post-approval safety study in adult patients undergoing CRRT using any ACCUSOL 35 solution(s). The primary endpoint is the presence or absence of visible precipitate in the CRRT lines used during the study.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Baxter Healthcare Corporation](#)

[Multiple centres: 17 centers are involved in the study](#)

## Contact details

### Study institution contact

Denise Van der Heijden [Regulatory@nikkisomedical.com](mailto:Regulatory@nikkisomedical.com)

[Study contact](#)

[Regulatory@nikkisomedical.com](mailto:Regulatory@nikkisomedical.com)

### Primary lead investigator

Elodie Clerc

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 27/06/2014

Actual: 27/06/2014

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### **Study start date**

Planned: 01/10/2014

Actual: 19/03/2015

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### **Date of final study report**

Planned: 30/08/2016

Actual: 30/09/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Baxter Healthcare Corporation

## Study protocol

[8822001-protocol-amend-1-2015jan12.pdf](#) (2.21 MB)

## Regulatory

## Was the study required by a regulatory body?

Yes

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## 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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Data collection methods:**

Combined primary data collection and secondary use of data

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#### **Main study objective:**

The objective of this study is to confirm the prevention of calcium carbonate precipitate formation during CRRT by the use of the updated ACCUSOL 35 solutions under normal clinical use conditions.

## Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Non-interventional, observational risk assessment

# Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(B05ZB) Hemofiltrates

Hemofiltrates

# Population studied

## **Short description of the study population**

Male and non-pregnant female patients were eligible for enrollment if they were at least 18 years of age and have been undergoing continuous renal replacement therapy (CCRT) using ACCUSOL 35 solution(s), without any concomitant medication added to the solution (except for supplemental KCl, if required), with the same CRRT circuit for at least 40 hours from Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Netherlands, Spain, Sweden and United Kingdom.

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## **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)
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### **Special population of interest**

Renal impaired

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### **Estimated number of subjects**

240

## Study design details

### **Outcomes**

Presence or absence of visible precipitate in the CRRT lines used during the study

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### **Data analysis plan**

The primary analysis will be to generate the upper bound of the 95% confidence interval on the true proportion of treatments having precipitate formation, based on the data from the evaluable treatments.

## Documents

### **Study results**

[accupass-report-body.pdf](#) (323.58 KB)

[Annexes.pdf](#) (9.87 MB)

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## 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**

Unknown