

# Italian healthcare resource consumption for patients on hemodialysis treated for chronic kidney disease-associated pruritus (CKD-aP)

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000619

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### Study ID

1000000619

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### DARWIN EU® study

No

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### Study countries

 Italy

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### Study description

Background: Chronic kidney disease-associated pruritus (CKD-aP) affects patients on hemodialysis. This study identified hemodialysis patients presumably affected or not affected by CKD-aP and integrated healthcare costs, from the perspective of the Italian administrative healthcare data. Methods: Through cross-linkage of Italian administrative healthcare data 2015-2017 (accrual period) in the ReS database, patients undergoing in-hospital/outpatient hemodialysis were selected. Cohorts with and without CKD-aP were created based on the presence/absence of supplies of CKD-aP-related treatment (according to common clinical practice and guidelines) and assessed in terms of CKD-aP-related treatments and mean healthcare costs per capita paid by the Italian National Health Service (Servizio Sanitario Nazionale - SSN). Results: Among about 5 million inhabitants, 1239 people on hemodialysis for  $\geq 2$  years were identified; of them, patients affected by CKD-aP were 218. Patients with CKD-aP (vs non-CKD-aP) were older and with more comorbidities. During the follow-up year, on average, the SSN spent € 37,065 per case, € 31,286 per control and € 35,988 per non-CKD-aP subject. High-efficiency dialytic therapies performed to people on hemodialysis with CKD-aP largely weighed on the overall mean annual cost. Conclusions: This real-world study identified patients on chronic hemodialysis potentially treated for CKD-aP. Interestingly, high-efficiency dialysis seems the most frequent and expensive choice for the treatment of CKD-aP. The discovery of appropriate and effective treatments for this condition might offer cost offsets.

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## **Study status**

Finalised

## **Research institutions and networks**

## Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

 Italy

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Institution

Not-for-profit

ENCePP partner

## Contact details

### Study institution contact

Carlo Piccinni [piccinni@fondazioneres.it](mailto:piccinni@fondazioneres.it)

Study contact

[piccinni@fondazioneres.it](mailto:piccinni@fondazioneres.it)

### Primary lead investigator

Letizia Dondi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 02/05/2024

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### Study start date

Actual: 03/06/2024

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

Actual: 03/06/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Funding for this study was provided by an unconditional grant from Vifor Pharma, Glattbrugg, Switzerland. The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing and publishing the report.

## 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 topic:**

Disease /health condition

Medical procedure

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**Study type:**

Non-interventional study

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**Scope of the study:**

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

During the 2015-2017 accrual period, patients with at least one in-hospital/outpatient hemodialysis procedure (ICD-9-CM code 39.95) were identified.

Patients with vs without CKD-aP were described at 1 year before/after index date for CKD-aP treatments and at 1-year follow-up for healthcare costs

**Main study objective:**

This study identified hemodialysis patients presumably affected or not affected by CKD-aP and integrated healthcare costs, from the perspective of the Italian administrative healthcare data.

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

## Medical condition to be studied

Chronic kidney disease-associated pruritus

## Population studied

### Short description of the study population

Patients with vs without CKD-aP, based on the presence/absence of supplies of CKD-aP-related treatment (according to common clinical practice and guidelines), and undergoing in-hospital/outpatient hemodialysis

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### Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 - 27 days)
    - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

## Study design details

## Setting

Italian inhabitants or potential beneficiaries of the SSN which is a universal coverage health system. Accrual period 2015-2017.

Overall observation period 2013-2018.

Selection criteria: in-hospital/outpatient hemodialysis procedure (ICD-9-CM code 39.95); reimbursed supplies of gabapentin, pregabalin, thalidomide and antihistamines, recommended by the current guidelines, and the performance of UV phototherapy were used as proxies of CKD-aP. Patients with CKD-aP were treated patients, while patients without CKD-aP were untreated patients, according to the treatments listed above.

Treatments had to be supplied 180 days before and/or 180 days after the hemodialysis, to be considered as associated to hemodialysis.

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## Comparators

an individual matched pair case-control analysis was performed to assess the average annual cost by healthcare administrative database and overall, through an even more realistic perspective. Matched variables were sex, age and local HA of residency.

Cases were people on hemodialysis potentially affected by CKD-aP, while controls were those without CKD-aP, according to the categorization by the presence or absence of CKD-aP-related treatments

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## Summary results

Of 1239 people on hemodialysis for  $\geq 2$  years, CKD-aP affected 218 patients. Patients with CKD-aP were older and with more comorbidities. During the follow-up year, on average, the INHS spent €37,065 per case, €31,286 per control and € 35,988 per non-CKD-aP subject.

High-efficiency dialytic therapies performed to people on hemodialysis with CKD-aP largely weighed on the overall mean annual cost.

## Documents

## Study publications

[S Calabria, L Manenti, G Ronconi, C Piccinni, L Dondi, L Dondi, A Pedrini, I Es...](#)

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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 source(s)

Database of Fondazione ReS

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Yes

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Unknown