Evaluating the utilisation of Urospir® (spironolactone) in paediatric and adult patients in the United Kingdom: A drug utilisation study using the Clinical Practice Research Datalink (CPRD) database

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Study Planned

Administrative details

EU PAS number

EUPAS1000000988

Study ID

1000000988

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A drug utilisation study on Urospir®, a non-aqueous oral solution of the potassium-sparing diuretic spironolactone, which aims to evaluate its real-world use. Urospir® is available in two strengths: 25mg/5ml and 50mg/5ml. The potential risk of medication error between the two Urospir® strengths has been listed as an important potential risk in the risk management plan.The DUS will be a retrospective cohort study, collecting data from CPRD Gold and Aurum. Any patient prescribed Urospir® from the license date up to the last collection date of the most recent database release will be eligible for inclusion. The study will evaluate patient characteristics such as age, gender, ethnicity, medical conditions. In addition, the study will describe the use of Urospir®, including the initial treatment regimen, indications for prescribing, potential off-label use, potential medication errors, changes to treatment, discontinuation, switching to alternative therapy and add-on therapy. Descriptive analyses will be undertaken.

Study status

Planned

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

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Institution | Not-for-profit | ENCePP partner

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Actual: 30/10/2025

Study start date

Planned: 22/06/2026

Data analysis start date

Planned: 29/06/2026

Date of final study report

Planned: 30/11/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Rosemont Pharmaceuticals Ltd

Study protocol

Protocol Abstract Spironolactone DUS.pdf (88.78 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A retrospective cohort DUS conducted in CPRD Aurum and CPRD Gold. Data will be collected on patients started on Urospir® (any strength) from August 2024 to data extraction (18-24 months after licensing).

Main study objective:

The overall aim of this drug utilisation study will be to characterise paediatric and adult patients prescribed Urospir® oral solution 25mg/5ml and 50mg/5ml.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Urospir

Study drug International non-proprietary name (INN) or common name

SPIRONOLACTONE

Anatomical Therapeutic Chemical (ATC) code

(C03DA01) spironolactone

spironolactone

Population studied

Short description of the study population

The study population will comprise all patients within CPRD Aurum and CPRD Gold who have received at least one prescription of Urospir® (25mg/5ml or 50mg/5ml strength) during the study recruitment period.

Age groups

- **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)

Estimated number of subjects

350

Study design details

Setting

This study will be conducted using routinely collected health data from primary care practices in the UK which contribute data to the CPRD Aurum and CPRD Gold databases.

In the UK, while spironolactone treatment is likely to be initiated by a specialist in secondary care (either as an inpatient or at an outpatient clinic), many patients will have medicines management transferred to their General Practitioner (GP) in primary care. Thus, the GP may take on the primary role of monitoring treatment, providing prescriptions, and altering the dose, when necessary, with the option of referral to secondary care if and when required. It is therefore anticipated that the use of the primary care CPRD databases, with additional data from relevant linked datasets, will capture sufficient detail on the utilisation of Urospir® to answer the study aim and objectives.

Comparators

Not applicable

Outcomes

The primary outcomes are: Patient demographics and clinical characteristics; Urospir® initial treatment regimen; Changes to Urospir® treatment; Off-label prescribing; Potential medication errors.

Summary results

Descriptive summary statistics will be produced to provide an overall description of the patient characteristics and the medical condition for which

Urospir® was prescribed. Patient ages will be categorised. Prescribing patterns of Urospir® 25mg/5ml and 50mg/5ml oral solution will be described, including off-label use. For numerical variables, frequencies and percentages will be presented, along with estimates of the mean (standard deviation) or median (interquartile range) where appropriate. Further details will be provided in the statistical analysis plan (SAP).

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)

Clinical Practice Research Datalink

Clinical Practice Research Datalink (CPRD) GOLD

Data source(s), other

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown