A multi-centre, retrospective real world study on the use of renin-angiotensin-aldosterone system inhibitors (RAASi) management in patients treated for chronic kidney disease alongside heart failure and/or type 2 diabetes mellitus. (SoMoR – UK (Study of Management of RAASi in UK))

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Study

Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/23377

EU PAS number

EUPAS23376

Study ID

23377

DARWIN EU® study

No

Study countries

United Kingdom

Study description

To investigate the use of renin-angiotensin-aldosterone system inhibitors (RAASi) in the real world UK NHS setting in patients with chronic kidney disease (CKD) stage 3 or 4 and at least one of the following: heart failure (HF), type 2 diabetes mellitus (T2DM)Where: CKD stage 3+ is defined as estimated glomerular filtration rate (eGFR) 30mls/min <eGFR<60mls/min HF is defined as presence of reduced ejection fraction and left ventricular ejection fraction (LVEF) <40% T2DM is defined as a confirmed diagnosis in medical records

Study status

Planned

Research institutions and networks

Institutions

Vifor Pharma

First published: 01/02/2024

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Institution

St George's University of London

First published: 01/02/2024

Last updated: 01/02/2024

Institution

St George's Hospital London, The Royal London London, Leicester General Hospital Leicester, England, Morriston Hospital Swansea, Wales, Dorset County Hospital Dorchester, England

Networks

NIHR Medicines for Children Research Network

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lisa Moore-Ramdin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/07/2017

Actual: 04/07/2017

Study start date

Planned: 30/03/2018

Date of final study report

Planned: 28/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Vifor Pharma UK Ltd

Study protocol

PT_SoMoR protocol_V4 1_21MAR2018.pdf(572.04 KB)

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:

Drug utilisation

Main study objective:

To describe prescribing modalities of RAASi in patients with CKD + either Heart Failure (HF) and/or Type 2 Diabetes Mellitus in the UK NHS setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Sentinel sites, Retrospective, observational

Study drug and medical condition

Medical condition to be studied

Chronic kidney disease

Population studied

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)

Special population of interest

Renal impaired

Estimated number of subjects

100

Study design details

Outcomes

Mean maximum tolerated daily dose of RAASi achieved (as percentage of target dose). Length of time on maximum tolerated daily dose of RAASiProportion of patients with HF who receive RAASi and MRALength of time on maximum tolerated daily dose of MRAProportion of patients with elevated serum potassium level (>5.1 mmol/L, >5.5 mmol/L or >6.0 mmol/L) Change in mean serum potassium, creatinine, urine protein and BP level over the observation period

Data analysis plan

The analyses will be descriptive and therefore the required sample size will be estimated based on precision instead of statistical power. A sample size estimate will be confirmed during protocol development but it is expected that approximately 100 patients will be sufficient to generate reliable results, as determined by relatively narrow confidence intervals.Data from all centres will be pooled for analysis. Categorical data will be described by the number (n) and percentage (%) of patients in each category. Continuous data will be described by number of observations, mean and standard deviation (SD) for normally distributed data or median and interquartile range for non-normally distributed data, and minimum and maximum values where relevant. Missing and invalid observations will be tabulated as a separate category. Rates will be reported with 95% CIs.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Data will be extracted from the electronic Patient Administration System (PAS), service databases and electronic (or paper) medical notes by the NHS direct clinical care teams or CRO researcher.

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