Clinical Study Report Synopsis	
Drug Substance	Observational
Study Code	D9484R00002
Edition Number	1.0
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NCT Number	NCT05184998

Description of the clinical outcomes of hospitalized patients with heart failure with different serum potassium levels: analysis of data from the China National Heart Failure Registration Study SPLENDID

Study dates:	First subject enrolled: 13Jul2022 Last subject last visit: 13Jul2022
Phase of development:	NA/Secondary analysis based on the CN HF study
International Co-ordinating Investigator:	Prof Zhou
Sponsor's Responsible Medical Officer:	Chang, **

This study was performed in compliance with Good Clinical Practice, including the archiving of essential documents.

Study centre(s)

Fudan University Zhongshan Hospital

Publications

None at the time of writing this report.

Objectives and criteria for evaluation

Table S1 Objectives and Endpoints

Objectives	Estimand description/Endpoints
Primary	
• To describe the clinical outcome of a composite of rehospitalization for worsened heart failure (HF) and cardiovascular (CV) death in hospitalized HF patients with different serum potassium (sK) levels	• The percentages of patients experiencing a composite of rehospitalization for worsened HF and CV death during study period in sK ranged (0, 3.5] mmo/L, (3.5, 5.0] mmo/L and (5.0, ~) mmo/L. • Rehospitalization for worsened HF is defined as any rehospitalization with HF as the first diagnosis during follow-up period of which the first discharge diagnosis is HF. • Study period is defined as 3 years or until death since patients enrolment. For detailed information, please refer to Section 3.5.
Secondary	
• To describe the clinical outcomes of hospitalized HF patients with different sK levels in terms of rehospitalization for worsened HF, CV death and all-cause death, respectively. • To describe the percentage of hyperkalemia in hospitalized HF patients. • To describe the RAASi treatment rate in hospitalized HF patients with different sK levels. • To describe the distribution of sK levels in hospitalized HF patients •	• The percentages of patients experiencing rehospitalization for worsened HF during study period in sK ranged (0, 3.5] mmo/L, (3.5, 5.0] mmo/L and (5.0, ~) mmo/L • The percentages of patients experiencing CV death during study period in sK ranged (0, 3.5] mmo/L, (3.5, 5.0] mmo/L and (5.0, ~) mmo/L • The percentages of patients experiencing all-cause death during study period in sK ranged (0, 3.5] mmo/L, (3.5, 5.0] mmo/L and (5.0, ~) mmo/L • The percentages of sK ＞5.0 mmol/L and ＞5.5 mmol/L in HF patients at baseline The baseline is defined as the first admission of hospitalization from Jan 1, 2013 to Jun 30, 2015 in CN-HF database. • The percentages of patients treated with RAASi in sK ranged (0, 3.5] mmo/L, (3.5, 5.0] mmo/L and (5.0, ~) mmo/L at baseline • The proportion of sK in ranges: (0, 3.5), [3.5, 5.0], (5.0, 5.5]，(5.5, 6.0], (6.0, 6.5], (6.5, 7.0], (7.0~) mmo/Lin HF patients at baseline

Study design

It was a secondary analysis based on the China National Heart Failure Registration Study (CN HF)HF), a hospital-based cohort study of HF.Data are from the CN-HF database. The CN-HF database consisted of 7,171 adult hospitalized HF patients enrolled from 45 hospitals in 20 provinces in China from Jan 1st, 2013 to Jun 30th, 2015. The CN-HF study cohort patients were followed up for 3 years or until death since enrolment.

Target subject population and sample size

Totally 6,950 HF patients with sK measurements on admission of hospitalization in CN-HF database were included.

Investigational product and comparator(s): dosage, mode of administration and batch numbers

This is an observational study base on CN-HF database.

Duration of treatment

This is an observational study base on CN-HF database. No study treatment.

Statistical methods

Sample Size Estimations:

A sample size of 6,950 was established for description of clinical outcomes. The study was descriptive in nature, hence the focus is on estimation of precision.

Statistical Analysis:

Statistical methods were primarily descriptive in nature.

For categorical data, the frequency and percentage of patients in each category were presented. Percentages were based on non-missing data unless otherwise specified.

For continuous data, descriptive statistics were presented as the number of patients (n), mean, standard deviation (SD), median, minimum and maximum.

For the study endpoints within this study (primary endpoint and secondary endpoints), the frequency and percentages in each category, as well as the 95% confidence interval (CI) of the percentages were presented.

Study population

Totally 6,950 HF patients with sK measurements on admission of hospitalization in CN-HF database were included.

Summary of results

Results: Among 6950 eligible patients, 5529 (79.6%) had normokalemia, 1113 (16.0%) had hypokalemia, and 308 (4.4%) had hyperkalemia. At baseline, higher proportions of patients with hyperkalemia were of older age (≥75 years), classified as New York Heart Association Class III/IV, and had hypertension, chronic kidney disease and HF with reduced ejection fraction (HF with preserved ejection fraction was least common) versus those with hypo- and normokalemia.

Conclusion(s)

These real-world data show that approximately 20% of Chinese patients hospitalized for HF had dyskalemia. Several baseline risk factors, including age ≥75 years, CV comorbidities and worse degree of HF, were most common in patients with hyperkalemia.