Association of eGFR slope and cardiovascular/renal events or all-cause deaths in Japanese database (eGFR slope and death)

First published: 08/05/2020

Last updated: 22/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS35224

Study ID

40994

DARWIN EU® study

No

Study countries

Japan

Study description

This is a longitudinal observational study using existing data with the primary objective: to assess the association between the annual rate of eGFR change with CV/renal events and all-cause mortality, adjusting for age, sex, CV medical history and baseline eGFR and/or UACR value.

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

Yasuhisa Ono yasuhisa.ono@boehringer-ingelheim.com

Study contact

yasuhisa.ono@boehringer-ingelheim.com

Primary lead investigator

Yasuhisa Ono

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/04/2020

Actual: 15/04/2020

Study start date
Planned: 22/04/2020

Actual: 22/04/2020

Date of final study report
Planned: 15/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

Protocol eGFR mortality cv renal event_final.pdf (549.22 KB)

Protocol final eGFR and mortality MDV May 19 2020.pdf (447.5 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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Primary objective: to assess the association between the annual rate of eGFR change with CV/renal events and all-cause mortality, adjusting for age, sex, CV medical history and baseline eGFR and/or UACR value

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic kidney disease

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

30.000

Study design details

Outcomes

all cause and cardiovascular mortality, myocardial infarction, stroke, and congestive heart failure.

Data analysis plan

1. Patient background: descriptive statistics will be provided on the age, sex, presence of medical history Elixhause comorbidity index score and prescription

of CV related medication by class during the baseline period. Sex, medical history, and CV related medication will be described as percentages to all eligible patients. 2. Slope of eGFR: descriptive analysis will be provided on the annual decline of eGFR overall (mean, 95% CI) and stratified by patients experiencing cardiovascular/renal and in-hospital mortality. The least square regression method will be used to calculate the slope and its 80%CI. Based on the slope all patients will be categorized into six groups3. Cox proportional hazards model will be applied to ②□ ⑥category of patients with ① as the reference group with time to event analysis conducted for each outcome.

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)

Administrative healthcare records (e.g., claims)

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