Clinical characteristics and disease burden of patients with diabetes mellitus combined with cardiovascular or chronic kidney disease based on regional medical database in Tianjin China

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Study Planned

Administrative details

EU PAS number

EUPAS38023

Study ID

41784

DARWIN EU® study

No

Study countries

China

Study description

The study aims to investigate the clinical characteristics, treatment, and economic burden of disease of Chinese diabetic/non-diabetic patients with/without established cardiovascular disease, chronic kidney disease, or at high cardiovascular risk, including: Primary objectives: describe the proportion of Chinese diabetic/non-diabetic patients with established cardiovascular disease, CKD, or at high cardiovascular risk including hypertension and hyperlipidemia, Secondary objectives: describe the demographic characteristics of the last visit for all patients, and the demographic characteristics of inpatients over time, investigate the clinical characteristic for all patients

Study status

Planned

Research institutions and networks

Institutions

West China Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Xin Sun

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2020

Actual: 27/11/2020

Study start date

Planned: 20/07/2021

Data analysis start date

Planned: 01/09/2021

Date of final study report

Planned: 30/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

Description of clinical characteristics, treatment and economic burden of disease

Main study objective:

The study aimsed to investigate the clinical characteristics, treatment, and economic burden of disease of Chinese diabetic /non-diabetic patients with/without established cardiovascular disease, chronic kidney disease, or at high cardiovascular risk

Study Design

Non-interventional study design

Cross-sectional

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)

Estimated number of subjects

100.000

Study design details

Outcomes

1) The proportion of diabetic/non-diabetic patients with established CVD, or CKD, or at high cardiovascular risk 2) The proportion of diabetic patients with

established CVD, or CKD, or at high cardiovascular risk among all diabetic patients 3) The proportion of non-diabetic patients with established CVD, or CKD, or at high cardiovascular risk, 1) Age at admission at the latest visit for all patients, as well as the trends for inpatients over time (2015, 2017, and 2019) 2) Gender at the latest visit for all patients, as well as the trends for inpatients over time (2015, 2017, and 2019) 3) Insurance payment at the latest visit for all patients, as well as the trends for inpatients over time (2015, 2017, and 2019)

Data analysis plan

Before analyses start, 200 randomly selected medical chart will be fully reviewed by well-trained experts to validate the accuracy and sensibility of code used to identify patients with cardiovascular disease or at high cardiovascular risk. The analyses will mainly describe the patient demographic characteristics, comorbidities, complications, treatment pattern and economic burden based on 40 hospitals EMRs of Tianjin regional database. Descriptive data will be provided. Characteristics presented as continuous data will be summarized through means, standard deviations, medians, minimum and maximum values, whereas, categorical data will be summarized as counts and proportions.

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