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

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Study   Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38027

EU PAS number

EUPAS38026

Study ID

38027

DARWIN EU® study

No

Study countries

☐ China

Study description

The study aimed 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: 1) describe the proportion of Chinese diabetic/non-diabetic patients with established cardiovascular disease, CKD, or at high cardiovascular risk including hypertension and hyperlipidaemia, 2) describe the demographic and clinical characteristics of Chinese diabetic/non-diabetic patients with/without established cardiovascular disease, CKD, or at high cardiovascular risk, 3) investigate the treatment patterns of Chinese diabetic/non-diabetic patients with/without established cardiovascular disease, CKD, or at high cardiovascular risk, 4) examine economic burden of disease of Chinese diabetic/non-diabetic patients with/without established cardiovascular disease, CKD, or at high cardiovascular risk, 5) explore the trends of clinical characteristics, treatment pattern, economic burden of inpatients over time (2015 and 2019 separately)

Study status

Planned

Research institutions and networks

Institutions

West China Hospital

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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

Study start date

Planned: 30/11/2020

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

Main study objective:

The study aimed 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

100000

Study design details

Outcomes

1. The number and proportion of diabetic/non-diabetic patients (outpatients and inpatients) with disease or risk from 2015 to 2019, patients will be defined as four groups (A-D) as mentioned above, 2. The demographic characteristics (including age, gender, ethic, insurance payment) of the lasted visiting for all

patients, as well as the trends for inpatients over time (2015, 2017, and 2019), 1.The clinical characteristics of the studied population of the lasted visiting for all patients, as well as the trends for inpatients over time, 2.Treatment pattern of inpatients and outpatients will be described respectively.

Data analysis plan

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. 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. All tests of statistical significance among different subgroups (age, gender, department, underlying diseases, etc.) will be two-sided unless otherwise specified, any test resulting in $p < 0.05$ will be considered statistically significant.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Tianjin regional database from 2015 to 201 . Based on Tianjin regional database, basic dictionaries including drug, diagnosis and examination were established from 40 hospitals in Tianjin.

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