Clinical characteristics, anti-hyperglycaemic treatment pattern and target attainment of type 2 diabetes mellitus patients in older population with or without albuminuria in China: A nationwide cross-sectional study

First published: 22/02/2017

Last updated: 12/12/2025

Study Planned

Administrative details

EU PAS number

EUPAS17922

Study ID

17923

DARWIN EU® study

No

Study countries

☐ China

Study description

Clinical characteristics, anti-hyperglycaemic treatment pattern and target attainment of type 2 diabetes mellitus patients in older population with or without albuminuria in China: A nationwide cross-sectional study

Study status

Planned

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Mei Mao

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 16/11/2015

Actual: 16/11/2015

Study start date
Planned: 15/03/2017

Data analysis start date
Planned: 15/03/2017

Date of final study report
Planned: 04/09/2018

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Study design:

It was a multi-centre, cross-sectional, non-interventional study

Main study objective:

To assess the level of blood glucose, measured by the proportion of patients attaining the blood glucose control target defined as HbA1c<7%.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1500

Study design details

Setting

Patients were recruited into the study in the order of their clinical visits scheduled. First 7 consented and suitable patients were recruited for each site on each day, or fewer if without enough patients. One study visit was planned for each patient. Clinical assessments were performed as part of routine clinical practice. Some laboratory tests results prior to the study were

used as source data as specified. All data required were entered into the Electronic Data Capture (EDC) System only after each patient had consented to participation.

Outcomes

The primary outcome is the proportion of patients attaining blood glucose control target defined as HbA1c<7%, according to 2015 American Diabetes Association (ADA) and 2013 Chinese Diabetes Society (CDS) guidelines.
Secondary outcomes:
- Renal function level of patients
- Treatment regimens for T2DM that patient are currently taking
- Proportion of macro vascular and micro vascular diabetic complications
- Proportion of Hypoglycaemic occurrenceProportion of Hypoglycaemia leading to therapy change
- Proportion of Anti-hypertension therapy usage
- Proportion of Lipid Lowering therapy usage
- Proportion of Anti-Platelet therapy usage

Data analysis plan

Descriptive statistics such as mean, standard deviation, median and range (minimum, maximum) will be used to summarize continuous variables. Counts and percentages will be used to summarize categorical variables. The chi-square test will be used to compare the categorical data between groups and the t-test will be used to compare the continuous variables that are normally distributed. For variables that are not normally distributed, non-parametric tests will be used.To identify the factors associated with overall blood glucose control, a stepwise logistic regression will be used.Missing data will not be imputed. Statistical significance will be assessed at a two-sided 0.05 level in an explorative way. All analysis will be conducted using SAS software.

Documents

Study results

1218-0174_Synopsis.pdf (9.6 MB)

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)

Disease registry

Other

Data sources (types), other

Exposure registry

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