Clinical characteristics and practice patterns of type 2 diabetes mellitus (T2DM) patients treated with oral antidiabetic drugs (OAD) in Japan: analysis of medical and health care database of the Medical Data Vision (MDV)

First published: 16/02/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS17761

Study ID

25010

DARWIN EU® study

No

Study countries

Japan

Study description

Appropriate use of oral antidiabetic drugs (OADs) including dose-reduction is important for patient’s safety in T2DM patients with renal impairment (RI). However, there are insufficient data on dose adjustment in accordance with the prescription pattern and the risk of RI of OADs, in particular DPP-4 inhibitors, in clinical practice in Japan. Therefore, we will investigate OADs usage conditions and dose selection in T2DM patients with RI in clinical practice in Japan

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

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Primary lead investigator

Takeshi Hirakawa

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/08/2016

Actual: 01/08/2016

Study start date

Planned: 01/03/2017

Actual: 01/03/2017

Data analysis start date

Planned: 10/03/2017

Actual: 10/03/2017

Date of final study report

Planned: 01/08/2018

Actual: 23/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to analyze the demographic and clinical characteristics of T2DM patients who have been treated with OADs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BA) Biguanides

Biguanides

(A10BB) Sulfonylureas

Sulfonylureas

(A10BF) Alpha glucosidase inhibitors

Alpha glucosidase inhibitors

(A10BG) Thiazolidinediones

Thiazolidinediones

(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

Dipeptidyl peptidase 4 (DPP-4) inhibitors

(A10BX) Other blood glucose lowering drugs, excl. insulins

Other blood glucose lowering drugs, excl. insulins

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Type 2 diabetes mellitus patients with renal impairment in clinical practice in Japan.

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)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

40000

Study design details

Outcomes

Demographic and clinical characteristics of patients who had a prescription of OADs. In case of comparing drugs within class, index date is defined as the date of first prescription for any study drugs as general name. Change of dosage is not counted as the index. Drug and dosage (based on daily dose) they are prescribed as there are different cut-offs for renal functions. In case of comparing drugs within class, index date is defined as the date of first prescription for any study drugs as general name. Change of dosage is not counted as the index.

Data analysis plan

For the primary objective, descriptive statistics of each compound and each class of OAD will be presented for the baseline demographic and clinical characteristics.For the 2nd objective, survival curves for discontinuation during the observation period in each patients group will be compared among patient groups prescribed with different classes of OADs to estimate retention rate of each therapy.For the 3rd objective, survival curves for discontinuation during the observation period in moderate or severe RI patients group prescribed OADs will be analyzed, if the sample size is enough.

Documents

Study publications

Kadowaki T, Sarai N, Hirakawa T, Taki K, Iwasaki K, Urushihara H. Persistence o...

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)

Other

Data sources (types), other

Insurance claims and diagnostic procedure combination (DPC) data provided by Medical Data Vision Co. Ltd (MDV).

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

Unknown