Burden of Disease of Chronic Kidney Disease (CKD), Type 2 Diabetes Mellitus (T2DM), and Comorbid T2DM/CKD in Alberta, Canada: A Non-interventional Study using Administrative Health Data

First published: 02/06/2020

Last updated: 02/08/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS35286

Study ID

42345

DARWIN EU® study

No

Study countries

Canada

Study description

The purpose of this study is to describe the incidence, prevalence, comorbidities and complication rates, treatment patterns and progression among patients identified with CKD, T2DM and comorbid T2DM/CKD. Further healthcare resource utilization and associated costs will be examined for patients with CKD. The study population represents three cohorts of adults in Alberta, Canada with: 1) CKD, 2) T2DM, and 3) T2DM/CKD. These cohorts will be defined using published definitions of diagnosis codes from the International Classification of Diseases, Ninth Revision, Clinical Modification/International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Canada. The diagnosis codes for these conditions can be in any position in the Discharge Abstract Database (DAD), National Ambulatory Care Reporting System (NACRS), or Practitioner Claims datasets between April 1, 2010 and March 31, 2019. Patients with CKD will also be identified utilizing laboratory tests of estimated glomerular filtration rate and albuminuria stage (based on albumin:creatinine ratio, protein:creatinine ratio and the dipstick test). Further inclusion criteria and published/validated algorithms were applied to define the three study cohorts of interest. A data request will be placed with Alberta Health to provide data for patients meeting the study inclusion criteria. Datasets of interest include the DAD, NACRS, Population Registry, Practitioner Claims, Pharmaceutical Information Network, Alberta Blue Cross as well as the Laboratory Services dataset from Alberta Health Services. The index date will be the first diagnostic code date (or laboratory test date for patients with CKD) within the case ascertainment period. Two years of retrospective data (from April 1, 2008) will be requested such that incident cases can be be identified. The study will provide evidence for the burden of disease and inform patient management for CKD, T2DM and T2DM/CKD in Alberta.

Study status

Ongoing

Research institutions and networks

Institutions

Medlior Health Outcomes Research

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Tara Cowling

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/11/2019

Study start date

Planned: 06/08/2020

Actual: 01/03/2021

Data analysis start date
Actual: 15/03/2021

Date of final study report
Planned: 31/12/2021

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

Describe the burden of disease among three different cohorts of patients: (1) patients diagnosed with CKD, (2) those with T2DM, and (3) those with T2DM and comorbid CKD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Chronic kidney disease

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

400000

Study design details

Outcomes

Determine the incidence and prevalence of the three cohorts in Alberta, 1. Comorbidity and complication profiles and rates (diabetic, renal, cardiovascular, mortality, fractures) - All cohorts 2. Factors that influence the progression of CKD in patients 3. Healthcare resource use and associated costs for patients with CKD by stage 4. Stage-to-stage progression of CKD across the follow-up years 5. Treatment patterns by year - All cohorts

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Data analysis plan

1. Incidence will be reported as new cases per 100000 2. Prevalence will be reported as cases per 100000 3. Comorbidity and complication profiles and rates will be described using descriptive statistics (means, medians, standard deviation, interquartile range, count, percent as appropriate) 4. Factors that influence the progression of CKD in patients will be assessed using logistic regression models, association of risk will be reported using odds ratios and 95% confidence intervals 5. Healthcare resource use and associated costs will be reported using mean and standard deviation for variables with count data, while the median and interquartile range will be reported for length of stay 6. Stage-to-stage progression across the follow-up years will be described

graphically utilizing a Sankey diagram 7. Treatment patterns by year will be described using frequencies and percentages for each medication

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