Monitoring for proteinuria in patients with type 2 diabetes mellitus (Proteinuria monitoring in type 2 diabetes)

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Study Finalised

Administrative details

EU PAS number

EUPAS9159

Study ID

14906

DARWIN EU® study

No

Study countries

- [ ] United Kingdom
- [ ] United States

Study description

Patients with Type 2 diabetes mellitus (T2DM) are at risk of developing diabetic renal complications. National Institute for Health and Care Excellence (NICE) guidelines recommend at least annual monitoring of diabetic patients for proteinuria. It is unknown if frequency of proteinuria testing varies by age, gender, renal complications, or antidiabetic drug therapy. This study aims to describe frequency of proteinuria monitoring, and whether the frequency of proteinuria testing varies by demographics (age, sex), smoking status, calendar year, renal complication or antidiabetic treatment. The proportion of proteinuria in patients with T2DM will also be obtained. This retrospective cohort study will identify T2DM patients who started treatment with an antidiabetic medication during 2007-2013 in Clinical Practice Research Datalink (CPRD). For simplicity, analyses focused on time to first proteinuria test. Monitoring rate was calculated as the number of patients with at least one proteinuria test during follow-up, divided by the sum of time to the first proteinuria test during follow-up, and during substratum of the follow-up period. Among patients with at least one test undertaken, the proportion of patients with the first test result status will be calculated. The findings from this study will be used for hypothesis generating for a future study.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Multiple centres: 2 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Paul Dolin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/03/2013

Actual: 04/03/2013

Study start date

Planned: 04/03/2013

Actual: 04/03/2013

Data analysis start date

Planned: 01/06/2013

Actual: 01/06/2013

Date of final study report

Planned: 31/12/2014

Actual: 20/11/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

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

This study aims to describe clinical practice using CPRD, specifically, how general practitioners monitor proteinuria in patients with type 2 diabetes

Data collection methods:

Secondary use of data

Main study objective:

The UK National Institute for Health and Care Excellence (NICE) guideline on diabetes recommends at least annual monitoring of type 2 diabetes mellitus patients for proteinuria. To date, little has been published on the frequency of proteinuria monitoring in T2DM, and its association with risk factors for renal complications. This study aimed to describe proteinuria monitoring in T2DM patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Type 2 diabetis mellitis patients who initiated antidiabetic drug therapy during 2007-2013 in the CPRD.

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

65790

Study design details

Outcomes

The primary outcome will be proteinuria monitoring rate, calculated as the number of patients with at least one screening test during follow-up, divided by the sum of time to the first proteinuria test during follow-up. The secondary outcomes will be the proportion of first test results as positive, negative or unknown for albuminuria/proteinuria and the proportion of second test results as positive, negative or unknown for albuminuria/proteinuria between 14 and 90 days after the first screening test.

Data analysis plan

This is a descriptive study. Only univariate analyses will be conducted in this descriptive study. There is no comparison group. Apart from descriptive analysis of primary and secondary outcomes, sensitivity analyses will be conducted to obtain monitoring rate by age, sex, smoking status at cohort entry, and calendar year among patients who did not have a diagnosis of albuminuria, proteinuria, nephritic syndrome or diabetic nephropathy at cohort entry.

Documents

Study publications

Liang H, Kennedy C, Manne S, Lin JHL, Dolin P. Monitoring for proteinuria in pa…

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 source(s)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

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