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

**First published:** 23/04/2015

**Last updated:** 02/07/2024

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

**First published:** 01/02/2024

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Institution

Multiple centres: 2 centres are involved in the study

## Contact details

**Study institution contact**

Paul Dolin trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

**Primary lead investigator**

Paul Dolin

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 04/03/2013

Actual: 04/03/2013

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**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

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**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

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**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

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**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.

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**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)

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**Special population of interest**

Other

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**Special population of interest, other**

Diabetes mellitus patients

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**Estimated number of subjects**

65.790

## 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.

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**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…

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# 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