# A retrospective nationwide cohort study to investigate the treatment of type 2 diabetic patients in Finland - DAHLIA

**First published:** 13/04/2015

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

Study Finalised

## Administrative details

**EU PAS number**

EUPAS8202

**Study ID**

39977

**DARWIN EU® study**

No

**Study countries**

Finland

**Study description**

There are about 280,000 people diagnosed with diabetes receiving medical treatment in Finland, most of them (85%) with type 2 diabetes mellitus (T2DM). T2DM is initially managed by life style changes only, but patients failing to control their blood glucose levels start eventually also using oral antidiabetic drugs (OADs). When the disease proceeds, many patients will need treatment with an injectable glucose-lowering drug (glucagon-like peptide-1 receptor agonist or insulin) in addition to OADs. Many new medicines have conquered the market in the recent years, but it is not completely known in detail how the glucose-lowering agents are used in a real-life setting. It would be important to understand the treatment journey in relation to disease progression and switches between different treatment levels in practice. The purpose of the study is to describe type 2 diabetes mellitus patients in Finland, especially their antidiabetic medication use (e.g. persistence, concomitance and switching), and to discuss the progression of the disease in terms of comorbidities and drug treatment. As a secondary objective the study includes health economic characteristics. As the study period lasts until 2013 (the latest year currently available from nationwide registers), the study setting includes also the newest drug groups on the market. A parallel study is conducted in Sweden, which makes between-country comparison possible. The enrolment of similar studies also in Norway and Denmark is under planning and therefore it would be feasible to compare the results from four Nordic countries in near future. Approximately 240 000 Finnish T2DM patients will be studied in 1998-2013 by using data from nationwide patient registers.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

## EPID Research Oy

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Institution

# Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Fabian Hoti

Primary lead investigator

# Study timelines

### Date when funding contract was signed

Planned: 02/09/2014

Actual: 02/09/2014

### Study start date

Planned: 31/01/2016

Actual: 11/12/2015

**Data analysis start date**
Planned: 30/11/2016

Actual: 03/03/2017

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**Date of final study report**
Planned: 30/09/2017

Actual: 14/11/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca Nordic Baltic

## Study protocol

ER-9489_AZ DAHLIA_Pharmacoepidemiological study protocol_v10_20150224_final_signed.pdf (1 MB)

ER-9489_AZ DAHLIA_Amendment to pharmacoepidemiological study protocol_v21_20170503_signed.pdf (870 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The purpose of the study is to describe type 2 diabetes mellitus patients in Finland, especially their antidiabetic medication use (e.g. persistence, concomitance and switching), and to discuss the progression of the disease in terms of comorbidities and drug treatment. As a secondary objective the study includes health economic characteristics.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

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**Medical condition to be studied**

Type 2 diabetes mellitus

# Population studied

**Short description of the study population**

Study population consists of T2DM patients in Finland identified by the following inclusion and exclusion criteria:

Inclusion criteria:

• A filled prescription for use of any blood glucose lowering (ATC: A10) drug between 1998 and 2013 or a special reimbursement for diabetes (refund code 103) by end of 2013.

Exclusion criteria:

• Patients who are entitled to special reimbursement for diabetes (refund code 103) with ICD010 diagnosis E10, E12, E13, E14 or E89.1 indicative of type 1 diabetes, diabetes related to malnutrition, other specified diabetes, unspecific diabetes or postprocedural hypoinsulinaemia, respectively, without refund 103 for E11 (i.e. other precondition for 103 than T2DM: ICD010 E11).

• Patients with hospital visits based on ICD010 E10, O24.0, E12, O24.2, E13, O24.3, O24.4, O24.9, E89.1 or P70.2 (referring to other diabetes mellitus than T2DM also during pregnancy or at birth) without E11 or O24.1

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**Age groups**

- Adolescents (12 to < 18 years)

- Children (2 to < 12 years)
- 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**

Type 2 diabetes mellitus patients

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**Estimated number of subjects**

350000

## Study design details

**Data analysis plan**

R language will be used for in data management for creating the analysis database and in statistical analysis for creating tabulations and graphics as well as in all statistical modelling. The annual prevalent and incident population will be described on yearly basis from 1998 to end of follow-up (year 2014). The summaries will include patient demographics, comorbidities, use of blood glucose-lowering drugs and use of other drugs. Incident population will be described on index date and prevalent population on the 1st of July. Both counts and percentages will be given.If a variable is totally missing it is excluded from the analysis. If a variable is missing for only some of the patients a missing data category is added and used in the analysis. The principles of the statistical analysis by objectives are outlined in protocol. More detailed

statistical analysis plans will be written separately.

## Documents

**Study results**

ER-9489-DAHLIA_Report synopsis_V1.0_20171114_signed.pdf (1.28 MB)

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**Study, other information**

ER-9489_Annex5_DoIForm_Johan Eriksson_signed.pdf (161.76 KB)

ER-9489_AZ DAHLIA_Pharmacoepidemiological study protocol_v20_20150827_signed.pdf (1.53 MB)

ER-9489_AZ DAHLIA_Pharmacoepidemiological study protocol_v21_20160607_signed.pdf (686.2 KB)

# 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.

This study has been awarded the ENCePP seal

**Conflicts of interest of investigators**

ER-9489_Annex5_DoIForm_20150331_signed_EPID.pdf (1.45 MB)

ER-9489_Annex5_DoIForm_20150408_signed_clinical expert and sponsor.pdf (1.24 MB)

ER-9489_Annex5_DoIForm_20170703_signed.pdf (3.59 MB)

**Composition of steering group and observers**

Composition of steering committee_20170503.pdf (34.04 KB)

EUPAS8202-8701.pdf (53.89 KB)

# Data sources

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

**Data sources (types), other**

Causes of Death Registry, National Prescription Register including drug purchases and reimbursement decisions, National Hospital Care Register, National Primary Care Register, National register for institutionalizations (other than hospitalizations), Sickness allowance register, Statistical pension register

# 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