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

PURI
https://redirect.ema.europa.eu/resource/39977

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.

Study status
Finalised

Research institution and networks

Institutions

EPID Research Oy
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Institution

Contact details

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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

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

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 data collection

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

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

Age groups
Children (2 to < 12 years)
Adolescents (12 to < 18 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)

Special population of interest
Other

Special population of interest, other
Type 2 diabetes mellitus patients

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)

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

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 data (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