Realization of the clinical practice guidelines for diabetes in Finland – A case study of the usability of electronic patient information systems and national registers to support evidence based decision making in health care (ER12-9451)

First published: 14/06/2013

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4117

Study ID

26958

DARWIN EU® study

No

Study countries

Finland

Study description

This is a retrospective database linkage study using patient information system data from selected primary and specialty health care organisations with linkage to nationwide registers. The overall objective of the study is to evaluate whether the electronic patient information systems and national registers can be used to support evidence based decision making in health care. The specific scientific objectives are to evaluate how the key elements of the Current Care guideline for diabetes (by the Finnish Medical Society Duodecim) are realized in practice and to investigate which factors explain successful implementation of treatment recommendations.

Study status

Finalised

Research institutions and networks

Institutions

EPID Research Oy

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pasi Korhonen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/12/2012

Study start date

Planned: 03/03/2014

Actual: 26/02/2014

Data analysis start date

Planned: 31/05/2016

Date of final study report

Planned: 30/09/2016

Actual: 09/08/2017

Sources of funding

- Other

More details on funding

Association: Pharma Industry Finland

Study protocol

Study protocol_ER12_9451_2013-04-30 Clean.pdf (978.75 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:

Other

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

Methodological, to study treatment guideline implementation

Data collection methods:

Secondary use of data

Main study objective:

To evaluate whether the electronic patient information systems and national registers can be used to support evidence based decision making in health care. To evaluate how the key elements of the Current Care guideline for diabetes are realized in practice and to investigate which factors explain successful implementa of treatment recommendations.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10A) INSULINS AND ANALOGUES

INSULINS AND ANALOGUES

(A10B) BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

All patients who have a diagnosis for diabetes (ICD-10 code E10*, E11*, E13* or E14*, or ICPC-2 code T89 or T90), a written prescription for diabetic medication (ATC code A10A* or A10B*), HbA1c value ≥ 6.5%, glucose tolerance test ≥ 11 mmol/L or nutrition counselling related to diabetes in the electronic patient information systems within the selected study sites, or patients who have purchased prescriptions for diabetic medication (ATC code A10A* or A10B*) or who have special reimbursement for diabetes (refund code 103) in the Social Insurance Institution (SII) registers during 2009-2012.

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

89000

Study design details

Outcomes

- Diabetes medications and related measurements- Frequency of follow-up measurements - HbA1c and S-LDL- Follow-up measurements every 12 to 15 months - Follow-up measurements every 1-3 years- Treatment decisions (other than diabetes treatment) based on follow-up measurements, - Mortality- Health care resource use: visits, contacts and hospital/PHC inpatient admissions.- Amputations of the lower extremities- Absence from work- Severe hypoglycemic events

Data analysis plan

The baseline characteristics will be presented as number of cases and percentages separately for each study site and for all sites combined. Appropriate statistical tests will be applied to statistically quantify any between site differences. Baseline characteristics include:• Age• Gender• Smoking• BMI• Dietary habits• Physical exercise• Concomitant disease • Concomitant medication• Laboratory measurementsRealization of current care guidelines will be evaluated for each site separately and for all sites combined. Appropriate statistical tests will be applied to statistically quantify between site differences. A (multi) logistic regression model will be used to model the study end-points with respect to the baseline covariates and study sites. When possible a binomial endpoint will be used (i.e. never vs. ever start of metformin or under 1 month vs. over 1 month to start of metformin).

Documents

Study results

9451_LTRY_Diabetes_report_V1_2017-08-09_with appendices.pdf (2.66 MB)

Study, other information

Annex5_Declaration of Interest_Tirkkonen_signed.pdf (1.62 MB)

Study publications

Niskanen L., Hahl J., Haukka J., Leppä E., Miettinen T., Mushnikov V., Sipilä ...

Sulamaa A., Prami T., Sipilä R., Linna M., Hahl J., Miettinen T., Leppä E., Hau...

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.

Conflicts of interest of investigators

Annex5_DoIForm_Pasi Korhonen_signed.pdf (1.57 MB)

Composition of steering group and observers

Annex5_Declaration_of_interest_FabianHoti_signed.pdf (1.57 MB)

EUPAS4117-4133.pdf (50.34 KB)

Signed code of conduct

Annex 3_ Declaration on compliance_signed.pdf (576.83 KB)

Signed code of conduct checklist

Annex2_Checklist of the code of conduct_signed_blackandwhite.pdf (204.19 KB)

Signed checklist for study protocols

ER12-9451_ENCePPChecklistforStudyProtocols_Signed.pdf (304.48 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring, Nationwide registers: Register for reimbursed medications Health insurance Sickness allowance register Hospital care register (discharge register) Hospital benchmarking database Causes of death registry

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

Unknown