Assessment of association between severe hypoglycaemia and use of detemir, glargine and NPH insulins (ER11-9417/ U1111-1120-7164)

First published: 16/12/2011

Last updated: 25/06/2025

Study Finalised

Administrative details

EU PAS number

EUPAS2278

Study ID

14838

DARWIN EU® study

No

Study countries

Finland

Study description

Hypoglycaemia events occur among diabetes patients who use insulin for treatment of diabetes mellitus. From the oral treatments supholnylurea (SU) products can also cause hypoglycaemia. Risk of hypoglycaemia is increased with age and duration of diabetes. Severe hypoglycemia can result in permanent neurological sequelae including neuronal cell death. Hypoglycemia also increases platelet aggregation and fibrinogen formation, which may accelerate vascular compromise in the brain. Among older patients with type 2 diabetes, a history of severe hypoglycaemic episodes severe enough to require hospitalization or an emergency department visit are associated with increased risk of dementia, particularly for patients who have a history of multiple episodes.The development of long-acting basal insulin analogues with improved pharmacokinetics, which are able to more closely replicate endogenous insulin secretion, has been shown to have a positive effect on the balance between effective glycaemic control and hypoglycaemic risk compared to NPH insulin. The primary aim of this retrospective follow-up study is to evaluate the differences in the incidence of the hospitalization and the secondary health care visits due to diabetes mellitus with hypoglycaemic coma between the different insulins.

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

Jari Haukka

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/01/2011

Study start date

Actual: 09/03/2011

Date of final study report

Planned: 14/03/2012

Actual: 18/06/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk Farma Oy

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

1) to estimate the incidence of severe hypoglycaemic coma, 2) to evaluate the recurrence of severe hypoglycaemic coma, and 3) to evaluate the number of severe hypoglycaemic coma events and duration of hospitalizations and secondary health care visits due to severe hypoglycaemic coma among diabetes patients using detemir, glargine, and NPH insulins, separately in the naïve and non-naïve populations

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Nation-wide retrospective register-based linkage study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10A) INSULINS AND ANALOGUES

INSULINS AND ANALOGUES

(A10BB) Sulfonylureas

Sulfonylureas

Medical condition to be studied

Diabetic coma

Population studied

Short description of the study population

Patients with diabetis mellitus suffering with hypoglycaemic coma between the different insulins.

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

Diabetes mellitus patients

Estimated number of subjects

138.000

Study design details

Outcomes

Severe hypoglycaemic coma (defined as: had led to hospitalization or outpatient hospital visit due to hypoglycaemic coma) among diabetes patients using detemir, glargine and NPH insulins. Switching between different insulin among diabetic patients using detemir, glargine or NPH insulins.

Data analysis plan

Crude incidence rates for detemir, glargine, and NPH-insulins, will be estimated for the first severe hypoglycaemia coma event and the recurrence of severe hypoglycaemia coma events, stratified according to the following variables: type of diabetes (T1, T2, undefined), age at start of follow-up, gender, calendar year of diagnose, time since start of insulin treatment, ever use of oral diabetes medication (A10BB) present use of other diabetes medication (A10A) and hospital district start of follow-up. The adjusted hazard ratio (HR) estimates for first occurrence and recurrence of severe hypoglycemia will be estimated using the conventional Cox's proportional hazards model. In addition, the causal effect of the treatments will be estimated by the use of the marginal structural models (MSM).The follow-up time in the analyses starts at the first purchase of detemir, glargine or NPH-insulin during 2000-2009 and ends at time of death or end of study period, whichever occurs first.

Documents

Study results

Mäkimattila poster presentation ADA2012.pdf (561.14 KB)

Study publications

Haukka J, Hoti F, Erästö P, Saukkonen T, Mäkimattila S, Korhonen P. Evaluation …

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 sources (types)

Administrative healthcare records (e.g., claims)

Disease 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

No