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

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/14838

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 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
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:
Human medicinal product
Disease /health condition

Study type:
Not applicable

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Data collection methods:
Secondary data collection

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 drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(A10A) INSULINS AND ANALOGUES
(A10BB) 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
138000

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

Data sources

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Drug dispensing/prescription data

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