Comparative effectiveness of insulin vs analogues to prevent complications of diabetes (CER insulin vs analogues)

First published: 08/07/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS6779

Study ID

6780

DARWIN EU® study

No

Study countries

Italy

Study description

The major challenge concerning the treatment of diabetes is representended by the prevention of vascular and metabolic diabetic complications and the related consequences for the health status of patients.Human insulin and/or its analogues are used to treat both type 1 diabetes mellitus, from its first onset, and type 2 diabetes, in its advanced phase. For both types of insulin, different formulations with different time to onset and duration of action, are currently available in order to provide patients with the most appropriate therapeutic option to mantain blood glucose concenration within the phisiological range throughout the day. In fact, different long-term follow-up studies of randomized clinical trials have found an association between inadequate plasma glucose control and the occurrence of diabetes complications. Insulin analogues possess benefit relative to human insulins in terms of glycemic control however, little is known about the long-term comparative effectiveness of insulin analogue with respect to human insulins in reducing the risk of cardiovascular and metabolic complications of diabetes. The main objective of this study was to assess the risk of diabetes complications in patients treated with insulin analogues against those using human insulin in a clinical pratice setting (i.e. Tuscany region). The secondary scope of this study was to evaluate healthcare costs respectively associated with the use of human insulins and insulin analogues (e.g. pharmacological treatment related to diabetes, hospitalizations, diagnostic procedures).

Study status

Finalised

Research institutions and networks

Institutions

Agenzia regionale di sanità della Toscana (ARS Toscana)

Italy

First published: 01/02/2024

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Institution | EU Institution/Body/Agency | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rosa Gini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/09/2013

Actual: 09/09/2013

Study start date
Planned: 30/09/2013

Actual: 18/11/2013

Date of final study report
Planned: 02/04/2014

Actual: 09/06/2014

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Eli Lilly Italia, ARS

Study protocol

Protocollo_Lilly.pdf (148 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess the effectectiveness of Analogue Insulin vs Human Insulin in reducing the risk of long-term microvascular, macrovascular and metabolic complications of diabetes.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10A) INSULINS AND ANALOGUES

INSULINS AND ANALOGUES

Medical condition to be studied

Diabetic hyperosmolar coma

Diabetic eye disease

Diabetic neuropathy

Diabetic nephropathy

Diabetic vascular disorder

Diabetic ketoacidosis

Diabetic retinopathy

Diabetic complication

Population studied

Short description of the study population

Patients present in the ARS databases and resident in Toscana in incident insulin treatment (ATC code: A10A*, at least 4 prescriptions in one year), in the period between January 2005 and December 2011.

Age groups

- Infants and toddlers (28 days – 23 months)
- 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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

6339

Study design details

Outcomes

Overall vascular and metabolic complications of diabetes mellitus. 1) Microvascular complications2) Macrovascular complications3) Metabolic complications

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Data analysis plan

This was a nested case-control in which cases were subjects with an incident inpatient diagnosis of vascular/metabolic diabetic complications. For each case, up to 3 sex, age and index date matched controls were randomly selected from the cohort.Incidence rate of diabetic complications was calculated by dividing the number of events by the sum of the person-time of the at risk population.Using a time-dependent exposure definition, Odds Ratio and 95% confidence interval of diabetic complications associated with current use of insulin analogue vs human insulin(≤1 year prior to the outcome) were estimated by conditional logistic regression and adjusted for selected comorbidities. As for the economic analysis, patients were allocated to specific insulin treatment considering the exposure observed during the 1st year of enrollment while costs where evaluated considering the 2nd year. A multiple linear regression analysis model was applied and adjusted for selected

confounder.

Documents

Study results

Report_Conclusivo_140609.pdf (180.88 KB)

Study publications

News on website of ARS: "I farmaci analoghi dell'insulina sono più efficaci a p...

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)

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