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

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Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/6780

**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).

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**Study status**

Finalised

# Research institutions and networks

## Institutions

## Agenzia regionale di sanità della Toscana (ARS)

Italy

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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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**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

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**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

## 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