Diabetes, Insulin and Malignancies Study New User Protocol (DIMSum)

First published: 24/01/2012

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS2333

Study ID

25978

DARWIN EU® study

No

Study countries

United States

Study description

This study utilizes a retrospective cohort design in which subjects with diabetes enter the cohort at the time of first use of insulin (glargine or NPH), and baseline information is obtained from a fixed period of time prior to first insulin

use. New users of glargine will be compared with new users of NPH insulin with respect to incidence of breast, colon and prostate cancer (individually) and all cancers combined (excluding non-melanoma skin cancer). Data will be obtained from electronic medical record systems and administrative databases in the US.

Study status

Finalised

Research institutions and networks

Institutions

Collaborative Studies Coordinating Center, Gillings School of Public Health, University of North Carolina at Chapel Hill

Ochsner Health System Louisiana, Partners HealthCare System Massachusetts, MedAssurant Maryland, Solucia Connecticut

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Haibo Zhou

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 09/04/2010

Study start date
Actual: 13/09/2010

Data analysis start date
Actual: 01/09/2011

Date of final study report
Planned: 30/06/2012

Actual: 22/07/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi-aventis

Study protocol

DIMSum New User Protocol 23Jan2012.pdf (446.62 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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to investigate whether use of the long-acting insulin glargine is associated with an increased cancer risk compared with use of human NPH insulin.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10AC01) insulin (human)

insulin (human)

(A10AE04) insulin glargine

insulin glargine

Medical condition to be studied

Diabetes mellitus

Population studied

Short description of the study population

Patients with diabetes aged 18 years and older at the time of first use of insulin (glargine or NPH).
For the analysis of data from Partners HealthCare System and Ochsner, individuals from their diabetes registries will be eligible to enter the new user cohort on January 1, 2005 (approximately) or later at the time of their first eligible prescription of either insulin glargine or NPH insulin. The earliest date when individuals in the MedAssurant database will enter the new user cohort is July 1, 2004. Individuals must have at least 19 months of continuous membership and pharmacy benefits prior to new user cohort entry; if membership is not well defined, a prescription is required in each of four 6-month periods prior to the first eligible prescription.

Age groups

- 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

61000

Study design details

Outcomes

The three primary outcomes include breast, prostate and colon cancer individually. The secondary outcome will be all cancers combined excluding non-melanoma skin cancers.

Data analysis plan

New users of glargine insulin will be compared with new users of NPH insulin with respect to cancer outcomes. We will use propensity scores to balance measured risk factors for cancer between these cohorts. To address the potential for confounding by BMI not measured in the claims database, we will assess the independent contribution of BMI towards the propensity score in 2 external validation studies using electronic medical records data. Hazard rates for each of the cancer endpoints will be estimated using a Cox proportional hazards model controlling for age and sex as well as any covariates remaining imbalanced after implementation of the propensity score. See full protocol for additional details and description of secondary and sensitivity analyses.

Documents

Study results

PMC3816915.pdf (147.61 KB)

Study publications

Stürmer T, Marquis MA, Zhou H, Meigs JB, Lim S, Blonde L, MacDonald E, Wang R, ...

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

Disclosure Buse long.pdf (81.75 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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