International Study of Incident Cancer-Breast Cancer (ISICA)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/3076

EU PAS number

EUPAS2480

Study ID

3076

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ France
- ☐ United Kingdom

Study description

Using case-control methodology, the ISICA study aims to primarily assess the relative risk of breast cancer associated with the use of individual insulins as compared to non-insulin use in patients with diabetes. Analysis will appraise individual mitigating or risk factors such as oral antidiabetic agents, type of diabetes, gestational diabetes, life-time history of BMI, reproduction related factors, oral contraceptives, hormonal replacement therapy, 1st degree relative cancer, socioeconomic status, behavioural risk, among other. Also, a number of biological parameters will be assessed (HER2, estrogens or progesterone receptors, circulating insulin). Firstly, a registry of patients with breast cancer, diagnosed with a first positive biopsy between January 2008 and June 2009 (time of alert), are identified through medical charts by a network of 88 centres across the UK, France and Canada. Secondly, case-subjects defined as those additionally suffering from diabetes, are identified. At least 1,000 of such patients are expected to meet this criterion and 750 to be included. Eligible subjects will be female, 18 years-old or more, without previous history of breast cancer, willing and able to participate. Control-subjects are defined as patients with diabetes fulfilling the same eligibility criteria and free of cancer at the time of match to cases. Controls will be independently recruited from general medical practices. An average of four controls will likely be matched to each case according to type of diabetes, age, country and region, totalling 3,000 controls. Exposure to insulin and other drugs will be collected from patients' general practitioners/pharmacy records. All patients will be interviewed for individual risk factors. Descriptive analysis andmultivariable modelling will be done for case-control comparisons. The study results are expected in 2012.

Study status

Finalised

Research institutions and networks

Institutions

Real World Studies, LA-SER Research

France

United Kingdom

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Institution | Other | ENCePP partner

Multiple centres: 672 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lamiae Grimaldi

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 28/12/2009

Study start date
Actual: 11/01/2010

Data analysis start date
Planned: 11/06/2012

Date of final study report
Planned: 17/09/2012

Actual: 19/09/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANOFI

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

the ISICA study aims mainly to assessthe association of breast cancer withthe use of individual insulins such asthe analogues glargine, lispro, andaspart, and human insulin formulationssuch as isophane and regularhuman insulin, compared with noninsulinuse in patients with 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

Breast cancer

Diabetes mellitus

Population studied

Short description of the study population

Female, 18 years-old or more, without previous history of breast cancer

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

5000

Study design details

Outcomes

It is a case control study. Cases are breast cancer patients with diabetes.

Data analysis plan

Exposures to insulin considered in the multivariate model will be categorised as:- Groups of insulin:a) Glargine useb) Aspart Insulin usec) Lispro insulin use d) Human Insulin usee) Other Insulin usef) No insulin use - Type of insulin use will be controlled for in relevant models:- Prandial use of insulin (yes/no)Odds ratios for each group of insulins will be estimated using the group “no insulin use” as the reference group. Comparisons between each group of insulin will be conducted. In particular, glargine insulin use will be compared with ‘non glargine insulins’ use ((b) to e)).

Data management

Data sources

Data sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

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