

# International Study of Incident Cancer-Breast Cancer (ISICA)

**First published:** 23/03/2012

**Last updated:** 22/10/2012

Study

Finalised

## Administrative details

### 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 and multivariable 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

**First published:** 23/03/2012

**Last updated:** 23/03/2012

**Institution**

**Outdated**

**Other**

**ENCePP partner**

Multiple centres: 672 centres are involved in the study

## Contact details

### Study institution contact

Lamiaie Grimaldi-Bensouda [lamiae.grimaldi@la-ser.com](mailto:lamiae.grimaldi@la-ser.com)

**Study contact**

[lamiae.grimaldi@la-ser.com](mailto:lamiae.grimaldi@la-ser.com)

### Primary lead investigator

Lamiaie 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 assess the association of breast cancer with the use of individual insulins such as the analogues glargine, lispro, and aspart, and human insulin formulations such as isophane and regular human insulin, compared with noninsulin use 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 use b) Aspart Insulin use c) Lispro insulin use d) Human Insulin use e) Other Insulin use f) 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

### 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)

[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